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MEETING
SCIENTIFIC REVIEW PANEL
ON
TOXIC AIR CONTAMINANTS

OAKLAND AIRPORT HILTON
FORUM ROOM
1 HEGENBERGER ROAD
OAKLAND, CALIFORNIA

WEDNESDAY, MAY 12, 1993
1:30 P.M.

Nadine J. Parks
Shorthand Reporter

MEMBERS PRESENT

Dr. James Pitts, Chairman

Dr. Charles Becker

Dr. Craig Byus

Dr. Stanton Glantz

Dr. Gary Friedman

Dr. James Seiber

Dr. Hanspeter Witschi

Staff (ARB)

Dr. Joan Denton

Genevieve Shiroma

Linda Martz

Bill Lockett

Bruce Oulrey

(OEHHA)

Dr. George Alexeeff

Dr. Lauren Zeise

Dr. Melanie Marty

Dr. Jim Collins

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P R O C E E D I N G S

--oOo--

CHAIRMAN PITTS: Good afternoon. We'll now commence proceedings with Item 1 on the agenda, SRP consideration of the Air Resources Board/OEHHA report, April, 1993, entitled, "Acetaldehyde as a Toxic Air Contaminant."

Joan Denton will be giving us the initial input.

DR. DENTON: Thank you, Dr. Pitts, and good afternoon, members of the Panel. Before I turn the presentation over to Linda, I want to mention that acetaldehyde is a federal hazardous air pollutant. And as part of the action the Board took in April on AB 2728, acetaldehyde has been listed as a toxic air contaminant.

The report you are reviewing today was developed under the AB 1807 air toxics identification program. And we have added clarifying language to the Executive Summary to reflect this.

If the Panel approves the health values for acetaldehyde today, these values will be used in the control phase.

Now, your action today does not dictate a risk management decision. During the control phase, the need, degree, and cost of control will be evaluated in a full public participatory process.

1 So now, I would like to introduce Linda Martz.
2 She has been leadperson on on Part A, and she will be
3 discussing with you the exposure assessment portion of
4 this document. Linda?

5 MS. MARTZ: Thank you, Dr. Denton. Good
6 afternoon, Dr. Pitts, members of the Panel, and audience.

7 Today, I will be summarizing the information we
8 have gathered on exposure to acetaldehyde in California.
9 I'll summarize and respond to the public comments we've
10 received during the comment period preceding this meeting
11 at the end of my presentation.

12 Our request for information from the public was
13 made in March, 1989. In September, 1989, we formally
14 entered it into our identification process.

15 In August, 1992, the first draft of the report
16 was released to the public for a 45-day comment period.

17 On September 17th, 1992, a public workshop was
18 held with SRB member Dr. Friedman in attendance.

19 In April of 1993, the SRP version of the report
20 was released for public comment.

21 My presentation this morning (sic) will include
22 sources and emissions of acetaldehyde, its atmospheric
23 persistence, outdoor and indoor concentration, an estimate
24 of potential lifetime cancer risk, and a summary.

25 Acetaldehyde is both directly emitted into the

1 atmosphere as well formed there as a result of
2 photochemical oxidation. Most of the acetaldehyde
3 directly emitted in California is a result of incomplete
4 combustion of hydrocarbons from mobile sources, agriculture
5 and management burning, and stationary sources.

6 Photochemical oxidation is the largest source
7 of acetaldehyde at ambient concentration.

8 The next slide shows the percent contribution of
9 each source to total emission. This pie chart shows the
10 relative contributions of photochemically generated
11 acetaldehyde and direct emissions to total concentration.

12 Photochemical formation contributes between 41
13 to 67 percent of atmospheric acetaldehyde with an average
14 56 percent, or 30,000 tons per year.

15 For stationary sources, there may be some
16 exposure to near source or hot spot concentrations of
17 acetaldehyde primarily through fuel combustion or process
18 emissions.

19 For purposes of this report, we did not evaluate
20 hot spot exposures pending the completion of the AB 2588
21 emission inventory.

22 The next overhead will show you a further
23 breakdown of direct sources of acetaldehyde. Of the
24 direct sources, stationary area sources account for the
25 majority or 62 percent of emissions. Of these stationary

1 area sources, 63 percent comes from wildfires, 32 percent
2 comes from agricultural and management burning, and five
3 percent comes from fuel combustion.

4 Mobile sources account for 32 percent of the
5 direct emissions and stationary point sources, such as
6 fuel combustion, refineries, and food preparation, were
7 responsible for the remaining six percent.

8 The atmospheric lifetime for acetaldehyde is
9 estimated to be approximately 12 hours. The major
10 removal mechanism is through hydroxyl radical reaction.
11 The ambient concentration analysis for acetaldehyde is
12 based on data collected at 19 stations statewide from the
13 ARB toxics monitoring network.

14 The overall estimated statewide population-
15 weighted annual exposure is estimated to be 2.3 ppbv.
16 This estimate is based on 24-hour sample averages. The
17 range of exposure between monitoring stations was from
18 1.1 to 3.3 ppbv.

19 Other investigators have reported data after
20 sampling acetaldehyde for two hours or less. These short-
21 term concentrations ranged from 2 to 39 ppbv.

22 Acetaldehyde is formed as a combustion byproduct
23 and is emitted indoors from a number of sources, including
24 cigarettes, fireplaces, wood stoves, and cooking. It is
25 present in some building materials and consumer products.

1 Indoor measurements are very limited. On average,
2 concentrations in homes and public buildings with and
3 without smokers present have been measured to range from
4 about 1 to 35 ppbv indoors.

5 This range reflects the addition of a new study
6 of indoor acetaldehyde in museums and a library. And we
7 plan to update our executive summary accordingly.

8 The Office of Environmental Health Hazard
9 Assessment estimates a range of cancer potency of
10 approximately 1 to 27 potential lifetime cancers per
11 million people. We note that the proposed risk value is
12 4.8 per million.

13 Dr. Alexeeff will discuss the basis for the
14 cancer potency value in his presentation.

15 Using the OEHHA staff's best value of 4.8 for
16 potential cancers per million per ppb, and the average
17 concentrations found in the outdoor environment, the
18 number of potential excess cancer cases due to outdoor
19 exposure to acetaldehyde is estimated to 10 per million
20 for a 70-year lifetime.

21 This corresponds to an estimated excess California
22 cancer burden of 288 for the 30 million people who reside
23 here.

24 In addition, OEHHA is recommending a chronic
25 reference exposure level of 5 ppb for noncancer effects.

1 Dr. Alexeeff will discuss the basis for the
2 development of the chronic reference exposure level in
3 his presentation. In summary, acetaldehyde is used in
4 a wide variety of products. The majority of acetaldehyde
5 is a product of photo-oxidation resulting in
6 approximately 30,000 tons per year. Direct source
7 emissions account for approximately 24,000 tons per year.

8 We estimated a statewide population-weighted
9 outdoor exposure to acetaldehyde of 2.3 ppbv, with indoor
10 concentrations ranging from 1 to 35 ppbv.

11 And finally, there is an estimated lifetime
12 individual risk of potential cancer cases of 10 per million
13 for outdoor exposures, which corresponds to a potential
14 excess cancer burden of 288 for a California population
15 of 30 million.

16 This concludes my presentation on the exposure
17 assessment portion of the document.

18 We have received three comment letters on the SRP
19 version of the report. They are from the American
20 Automobile Manufacturers Association, Chevron Research &
21 Technology Company, and Morrison & Foerster, attorneys
22 representing the American Bakers Association.

23 We will respond to the first letter from the
24 American Automobile Manufacturers Association. And the
25 second and third letters, which concern health effects, will

1 be addressed by Dr. Alexeeff.

2 The letter is composed of four paragraphs and each
3 paragraph represents a comment. So, I'll start taking
4 them in order.

5 Comment 1: The American Automobile Manufacturers
6 Association is concerned that the emissions inventory
7 data used from 1987 is dated and does not reflect a more
8 realistic mix of vehicles with catalytic converters.

9 Our response: In our report, we used only
10 emission inventory data which has been thoroughly
11 evaluated. More recent data has now been thoroughly
12 reviewed under ARB's rigorous quality assurance program.

13 In addition, we reviewed the more recent Auto/Oil
14 data and included a discussion of that data in our report
15 under the trend section.

16 Comment 2: AAMA is concerned with the emission
17 factors shown in Tables 2 and 3 of Appendix A, which lists
18 identical acetaldehyde fractions from catalysts equipped,
19 noncatalysts, or diesel-fueled vehicles regardless of the
20 type of vehicle. AAM believes that the fraction of
21 acetaldehyde and total hydrocarbons is not the same for
22 different classes of engines and fuels.

23 Our response: We agree with the comment and would
24 use speciated emission factors if they were available.
25 However, we used the best emissions factors available.

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1 We plan to add the following footnote to both
2 tables: Because of the lack of specific data for these
3 engines and fuels, we assumed acetaldehyde emissions from
4 different classes of engines and fuel to be similar.

5 I'm starting on the third paragraph, Comment 3:
6 AAMA disagrees with using the urban airshed model, the UAM,
7 to estimate the amount of acetaldehyde produced
8 photochemically because the model used data from a
9 summer high ozone day in the most polluted region of
10 California.

11 AAMA believes that using such data will result
12 in much higher concentrations than if a more typical
13 day had been used.

14 And our response: We acknowledge that a worst-
15 case scenario was used for the UAM analysis of secondary
16 acetaldehyde. UAM is the only model available to assess
17 the impact of secondary acetaldehyde and by convention
18 is the accepted model routinely used for urban
19 photochemical modeling.

20 We do not at this time have an alternative
21 database to use with the UAM. We note that the use of
22 the UAM doesn't affect the overall estimation of risk,
23 since the risk was calculated using an annual average
24 ambient concentration derived from the air toxics monitoring
25 network. The information was provided to give a

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1 comprehensive picture.

2 Comment 4, the last paragraph: AAMA suggests
3 that Figures III-1 and III-2 be changed to reflect the
4 contribution of on-road and other mobile sources to the
5 total emissions of acetaldehyde and to direct emission
6 sources of acetaldehyde by splitting the single slice,
7 labeled "Mobile Sources" into two slices labeled "On-road
8 Mobile Sources" and "Other Transportation Sources."

9 The mobile source could be separated further
10 into vehicle type and fuels.

11 And our response: We plan to change the mobile
12 sources' portion of the pie chart in Figures III-1 and
13 III-2 to reflect on-road mobile and other transportation
14 sources.

15 In the text, we plan to add language to describe
16 the contribution of vehicle types and fuels to
17 acetaldehyde emissions.

18 Dr. Alexeeff will address the health-related
19 comments during his presentation.

20 This completes my presentation, and I will be
21 glad to answer any questions the Panel may have.

22 CHAIRMAN PITTS: Thank you very much, Linda.
23 This is open for discussion now. I might ask for a point
24 of clarification. Much of what you have said is in in the
25 Executive Summary, right?

1 DR. DENTON: That is correct.

2 CHAIRMAN PITTS: So, almost all of what you said,
3 including the health effects, are in the Executive
4 Summary? That's not a criticism. I want to be sure
5 that we do get to the Executive Summary, which is what,
6 as we've always said, what most people read, and then go
7 to the individual -- which is Part A and B. I heard
8 things in your presentation that sounded to me like
9 it came out of the Executive Summary.

10 DR. DENTON: Yes, Dr. Pitts.

11 CHAIRMAN PITTS: And that's fine. We might
12 open both of them up for discussion.

13 DR. DENTON: Dr. Pitts, what Linda said was
14 from the Executive Summary and for the exposure portion,
15 of course, that is also in Part A.

16 So, except for her comments, of course, in
17 responses to the letters.

18 CHAIRMAN PITTS: Sure. Okay. So, we're open
19 to the exposure comments in the Executive Summary and,
20 then, of course, in Part A. We'll start over here.
21 Dr. Friedman?

22 DR. FRIEDMAN: I had a question about both your
23 presentation and what you wrote on page 7 and 8, where
24 you said, "Formation in the atmosphere. . ." you're
25 talking about the formation in the atmosphere by

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1 photo-oxidation.

2 For those of us who don't know much about
3 atmospheric chemistry, photo-oxidation of what? Is it
4 pollutants or is it something that naturally is occurring
5 in the atmosphere, or what? You just sort of leave it
6 blank.

7 I noticed on page A-54, you did speak of
8 degradation of organic pollutants, but I think that should
9 be made earlier -- clear earlier on page 7 and 8 also.

10 MS. MARTZ: I think you're requesting some
11 background on photo-oxidation?

12 DR. FRIEDMAN: Yeah. I just wanted to know of
13 what? Is that something that's naturally occurring in
14 the atmosphere or something that's being put in there as
15 a pollutant?

16 MS. MARTZ: No. It would be a hydrocarbons
17 emitted. Hydrocarbons would be the precursors. And then
18 the main pathway would be would be with the hydroxyl
19 radical. So, the hydrocarbons of concern would be perhaps
20 the propenes, propionaldehyde, 2-butoxy radical --

21 DR. FRIEDMAN: I think it would be helpful to
22 put that into the report. Because, otherwise, it seems
23 to, you know, you don't know where it's coming from and
24 how one might be able to attack this problem of the large
25 contribution of photo-oxidation to the atmospheric content

1 of acetaldehyde.

2 MS. MARTZ: There's more of what I just said in
3 Chapter 5 under the atmospheric chemistry.

4 DR. DENTON: So, Dr. Friedman, if we're
5 understanding you, we could bring that information up
6 into the Executive Summary.

7 DR. FRIEDMAN: Okay.

8 DR. DENTON: And say, "emitted hydrocarbons."

9 DR. FRIEDMAN: Put it in earlier in your Part A,
10 pages 7 and 8, where you just speak of photo-oxidation,
11 but you don't say of what. I think you should at least
12 introduce the topic there.

13 DR. DENTON: Okay.

14 CHAIRMAN PITTS: Yeah. And actually, you're
15 correct. It's both anthropogenic and natural sources.
16 They both produce it. So, basically, better to use the
17 term "VOC." You're talking volatile organic compounds,
18 some of which are hydrocarbons -- just carbon and
19 hydrogen -- some of which are oxygenates, which also can
20 produce acetaldehyde. So, you really should mention the
21 fact and look into the possibility of natural sources of
22 VOCs that might be precursors to acetaldehyde.

23 So, it's a good question. And bringing it in
24 early on would be helpful in the Executive Summary and in
25 Part A. It is in there. I've read it. And if you read

1 Atmospheric Chemistry and subscribe -- but when you go
2 into atmospheric chemistry, some of you may get a little
3 bit of a shock that I get when I read Part B and look
4 into biochemical transformations and all these exciting
5 things. I sort of look at them and say, (whistle).

6 So, I think it should be there. I agree with
7 you.

8 DR. FRIEDMAN: Yes. Are there some implications
9 for dealing with this problem? You list the sources,
10 like combustion and, you know, vehicles and so on. And
11 so, one can think of things one could do about reducing
12 acetaldehyde from those direct sources. But are there some
13 implications for this indirect pathway of something else
14 getting into the atmosphere and then being photo-oxidized?
15 I mean, could something be done about that, too?

16 DR. DENTON: You're right, Dr. Friedman. And
17 again, during the control phase, all aspects of this will
18 be looked at.

19 CHAIRMAN PITTS: But I think his point is that it
20 should be discussed in here, because the control phase
21 will be driven by what has been presented in Parts A and B.

22 DR. BECKER: Well, I think there was some confusion,
23 because one of the commenters asked whether alcohol was
24 converted in the environment to acetaldehyde by alcoholic --

25 CHAIRMAN PITTS: Oh, yes.

1 DR. BECKER: -- so they weren't clear where it
2 was coming from.

3 CHAIRMAN PITTS: Which is a major point we'll get
4 to. Okay. Stan?

5 DR. GLANTZ: I'll pass for now.

6 CHAIRMAN PITTS: You'll pass. On first down?

7 DR. GLANTZ: I just came from Stockton. But I
8 didn't speed for the record, so --

9 (Laughter.)

10 CHAIRMAN PITTS: You're on the record as being
11 straight. All right. Chuck?

12 DR. BECKER: No questions.

13 CHAIRMAN PITTS: Jim?

14 DR. SIEBER: I agree with the comment. I just
15 wanted to add that from my point of view, this is the
16 weakness of -- not the document, but the whole monitoring
17 system in California. We don't know what the natural
18 background level is of a lot of these things, because all
19 of our monitoring stations are in cities, very few of them
20 located in rural, or forested, or agricultural fields.

21 So, there could be major sources of acetaldehyde,
22 quite frankly, that we don't know about. And we're not
23 even sure that the urban sources are the major sources,
24 because we don't have the comparable data from outside the
25 cities.

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1 CHAIRMAN PITTS: I have a couple of comments
2 that, as I read this, are relevant also, actually I think
3 to the impacts of acetaldehyde. And that is -- and it's
4 mentioned -- I didn't see it in the Executive Summary,
5 but I saw it somewhere -- maybe in Part A or maybe it's
6 in here -- mentioned that in the photo-oxidation, you
7 photo-oxidize volatile organic compounds to form
8 acetaldehyde. It happens through hydroxyl radical, the
9 usual oxidation systems in the atmosphere. But the fate
10 of the formation -- the fate of the acetaldehyde, a major
11 fate of major concern to the medical community was of
12 concern to the people in Pasadena in 1952, and '3, and '4,
13 till it as discovered, and that's peroxy to a nitrate.
14 Acetaldehyde is the major source in urban air of PAN,
15 and PAN, if any of you -- it's an incredible acclimator.
16 And it is -- you know, the word done in Santa Barbara
17 by what's his name, some professor in Santa Barbara did
18 work on this, did a health effects study, lung study.

19 DR. DENTON: Stephen Horvath.

20 CHAIRMAN PITTS: Horvath. So, PAN is a major
21 concern. So, that's a good point. In fact, Brazil went
22 over -- certain cities in Brazil -- I think Sao Paulo --
23 and this should be brought up now in this report. This is
24 important business, because I think this is going to be
25 read in terms of what contribution can you make in terms

1 of control, which is another thing I think you're getting
2 into. What would you control?

3 They went to ethanol fuels. They had a gasoline
4 shortage of the regular gasoline. They went to ethanol,
5 good old ETOH. And I've had friends of mine, colleagues,
6 who've been down and making measurements. And they're
7 just streaming with tears. They're saying, "Now, they're
8 trying to go back to gasoline because of the health
9 impacts."

10 So, I think you should have a section in here
11 on -- you have one on the formation, but you should have
12 one on atmospheric fates, and what are the implications.
13 So, there should be a paragraph, something to do with
14 this in Part A as well as in the Executive Summary, that
15 this is a major problem in terms -- not necessarily --
16 I have no information as to the possible carcinogenicity,
17 but I can tell you a few million people who grew up in
18 the days when we had PAN produced in large amounts. That
19 is a very serious issue.

20 Now, it's also a plus issue, which could be then
21 brought into effect, because, in fact, the catalyst
22 controls have been cutting way back on VOCs and cut even
23 faster on acetaldehyde. That's removed more readily than
24 the initial hydrocarbon, because it's already partly
25 oxidized. So, a catalyst will hit that harder than it will

1 hit, say something like an ethane, which can oxidize to
2 it, but it's slow. Are you with me on this?

3 DR. FRIEDMAN: No.

4 CHAIRMAN PITTS: Well, your catalyst can knock
5 out an oxygenated species faster than the original
6 hydrocarbon, so you're already part way along the line.

7 So, formaldehyde comes out like a shot from a
8 catalyst; whereas, methane is slow, because you haven't
9 started it yet. Okay? But we can talk about the
10 chemistry later. But that basically is an important
11 point.

12 So, the catalyst system, once again, has won.
13 The ARB catalyst tight controls on VOCs has turned out to
14 make a real progress, and that's one of the reasons why
15 eye irritation, you don't hear that much -- you don't
16 hear the severity taking place these days. Okay? So,
17 you might want to think about that.

18 Then, I don't think I saw -- and I looked
19 carefully through this and this (holding documents for
20 display). And it's relevant. I don't know if it's
21 politically correct now. But it's relevant. I think that
22 I just heard yesterday or a couple of days ago, that there
23 will not be a proposed energy tax -- this is sort of
24 floating out of Washington -- on ethanol. And I think I'm
25 correct about that. Now, that poses a significant question.

1 Because if you increase the use of ethanol in a fuel,
2 like E-85 -- that's ethanol, and 85 is gasoline, and you
3 go that route, if you think we have problems with
4 acetaldehyde now, you ain't seeing through tears. You
5 know, "I'm driving with tears in my eyes. . . ."

6 (Addressing the court reporter) Don't take that
7 down.

8 (Laughter.)

9 CHAIRMAN PITTS: But I'm dead serious. This is
10 a major concern about alternate fuels. And I have seen
11 the major -- ADM -- the major companies are pushing
12 ethanol as a fuel. It's a real consideration. And if you
13 have a properly equipped catalyst car that's all working
14 fine, probably that may be okay. But I can assure you,
15 in general use, it's going to be a real problem. So, we
16 should address ethanol and E-85 as to what the implications
17 are, as we did for formaldehyde when we discussed
18 methanol, if you recall.

19 So, that would be something we'd want to -- and,
20 again, in the context that you make acetaldehyde, you're
21 making PAN plus a bunch of other things. Okay? So, those
22 are sort of general comments that we might want to think
23 about. And I'm going to just quickly go through the
24 Executive Summary here, just real quick. I've got a
25 couple of comments. Some of these are trivial. And, Joan,

1 I'll give this thing to you.

2 DR. DENTON: Great.

3 CHAIRMAN PITTS: But one thing I noticed that,
4 on page 3, you said -- and this is relevant to the
5 subsequent discussion today about our 189 HAPs, and in
6 the sense -- and the criteria that Stan and Jim have been
7 the numbers you've been putting on these things -- these
8 various categories.

9 It says, "Why was acetaldehyde evaluated as a
10 TAC?"

11 It's on page 3. And down here about the fourth
12 line from the bottom of that paragraph, "Furthermore, the
13 OEHHA staff agrees with the United States EPA that
14 acetaldehyde is a 'probable human carcinogen.'"

15 Now, is there an IARC number? Has IARC
16 examined acetaldehyde as a potential carcinogen?

17 DR. DENTON: Dr. Alexeeff, of course, will address
18 it in his portion, but the IARC has classified acetaldehyde
19 as a "possible" human carcinogen.

20 CHAIRMAN PITTS: Well, then, I think that should
21 be in here, too. You should say that the EPA said that
22 it's "probable." And you said that it was a 2-B, right?
23 Later, in another part of the document, it was 2-B.

24 Now, that's a little confusing, because IARC's
25 2B means possible carcinogen. So, you want to be sure and

1 clarify that the EPA did, in fact, say "probable, 2B,"
2 and IARC, "possible." Probable is 2A for IARC. So,
3 you want to get that clarified, and put both of them in,
4 because in your criteria we'll be discussing later today
5 on handling 189 HAPs, among those criteria are some points
6 that were given for IARC and EPA numbers or categorizations
7 as probable/possible.

8 DR. DENTON: That's right.

9 CHAIRMAN PITTS: We'll get that in there. Okay.

10 DR. DENTON: And I think Dr. Alexeeff actually
11 will be discussing a few of the changes for this question
12 in his presentation.

13 CHAIRMAN PITTS: This is just for clarification,
14 and be sure they're in there. And then, back here on page
15 4 -- and in here somewhere be sure to put in -- 4 and 5 --
16 be sure to put in E-85. You're talking about gasoline
17 specifications, and this should go in the Executive
18 Summary that there are problems with ethanol as a major
19 source when used in fuel for motor vehicles. And that
20 should be discussed appropriately somewhere in there.

21 Now, then, I was a little confused, and you might
22 want to clarify for us -- on page 6, "Is there evidence
23 of indoor air exposure to acetaldehyde?" You start
24 out there by saying, "Surveys have shown that indoor air
25 concentrations. . . can be about two to eight times higher

1 than outdoor. . ."

2 And then, if you take the numbers for indoor
3 that you find back on page A-33, and you have Table IV-2.
4 You have tables that give the maximum and minimum of the
5 measurements of -- Genevieve, of your program, of the
6 ARB program. And the maxima and minima that you got from
7 your study in '88, as I see, Genevieve, there's no way
8 eight times higher, other than being in a bar -- a bar
9 in Toledo -- ut other than in a bar or a tavern where
10 there's heavy smoking. So, I think you want to be --
11 you're talking about SCAQ's data. Now, that's another
12 issue. You should be very careful to separate what the
13 SCAQ's data were from '87, along with your new approach,
14 and you've got monitoring, your own ARB stations. And
15 if you look at your own data, you might want to try to
16 make a decision -- which one do you want to emphasize?

17 Because the tables in there are your data. And
18 I don't think that -- and then, when you look at the
19 indoor numbers, I don't see indoor numbers other than
20 that that's in the bar, the tavern, that would be two to
21 eight times higher. So, you want to reconcile and decide
22 which numbers you're going to say indoor compares to
23 outdoor. What set of data are you going to take?

24 DR. DENTON: Dr. Pitts, we realize that this
25 needs to be revised. And Linda kind of alluded to it, in

1 the fact that we do have this newer study on on museums
2 and a new concentration to put in here.

3 So, we'll have to, for this question, go through
4 this thoroughly and be sure that all our numbers are
5 consistent.

6 CHAIRMAN PITTS: Well, that kind of concerns me,
7 though. I think that we're looking -- the Panel's been
8 looking at things that we've had input, but there's still
9 more -- I know we've talked about this, so it isn't that
10 you haven't commented. But I missed some things, and
11 some things weren't there, too. So, you're saying then
12 that these will be revised appropriately then?

13 MS. MARTZ: Yes.

14 DR. DENTON: Yes, we need to revise both the
15 indoor air, our range of concentrations in that second
16 paragraph as well as how much higher indoor concentrations
17 can be relative to outdoor.

18 CHAIRMAN PITTS: And would you make decisions
19 based on the highs that you see in terms of the ARB
20 data from the '88 studies and your current data? Isn't
21 that right, Genevieve? Or will you be using SCAQ's, which
22 is --

23 DR. DENTON: Conventionally, Dr. Pitts, we've used
24 the indoor concentrations as we --

25 CHAIRMAN PITTS: I'm talking about outdoor levels.

1 DR. DENTON: Yes, as related to the annual average
2 for the outdoor network.

3 CHAIRMAN PITTS: Has been your --

4 DR. DENTON: That's our conventional way.

5 CHAIRMAN PITTS: Then maybe you want to be
6 consistent then with the ARB data.

7 DR. DENTON: Right.

8 CHAIRMAN PITTS: Okay. That's not a big -- I
9 think the data are very good, and I think the numbers
10 are very important. That's a major database and an
11 important database that's worth the time and effort that
12 I know has gone into it. That's great. Okay. Then,
13 that's fine.

14 On the bottom of page 7, just from a quick --
15 I'm trying to move as rapidly as possible. But it says
16 at the bottom of the page, we're talking about the
17 lifetime of acetaldehyde, 12 hours. And I'm sure that's
18 right. That sounds reasonable. But then it says, "which
19 is sufficient time to allow dispersion throughout an air
20 basin."

21 I think that under stagnant air conditions, 12
22 hours is not sufficient to disperse throughout an air
23 basin. And I can visualize episodic -- I think you call
24 them tule fogs when you go up to a place called Sacramento.
25 And there, if you've got major emissions from major

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1 sources, motor vehicle emissions and maybe burning
2 ethanol, you may find that this isn't dispersing that
3 rapidly. So, you might even add, which under usual,
4 normal conditions, or something -- normal meteorological
5 conditions is sufficient time. Otherwise, it gives
6 the impression that it's reverse. That's just sort of a
7 minor point.

8 Okay. Now --

9 DR. SEIBER: Jim, can I put something in?

10 CHAIRMAN PITTS: Put it in.

11 DR. SEIBER: You said something that caught my
12 attention there. If this is a calculated number, could
13 we say, "is calculated to be," instead of -- it gives
14 the impression that it really is 12 hours. "... is
15 approximately 12 hours."

16 CHAIRMAN PITTS: It's estimated.

17 DR. SEIBER: It's calculated to be 12 hours.

18 CHAIRMAN PITTS: That's right. Calculated. You
19 got it. Absolutely. It could be an average, average OH
20 levels, et cetera. Okay.

21 And then, here on page 9 might be a place where
22 you could put in under evidence that acetaldehyde is a
23 public health hazard, exposure to animals -- page 9,
24 second paragraph. Something should be there, as a public
25 health hazard, that's where you could put in PAN again.

1 That is its fate. It forms PAN in the atmosphere, and
2 that -- I'm not prepared to say you talk about Horvath
3 about -- and the gentlemen here about what that would
4 be, but it sure does make a -- by the way, PAN is also
5 a severe, major sitotoxidant. It just wipes -- you know
6 that. It wipes out plants, pinto beans. In fact, that was
7 one of the original things that they found -- pinto beans
8 went like that (snapping fingers). It wasn't the ozone
9 so much; it was the PAN at very low levels.

10 So, anyway, you might put something in there
11 to that effect to indicate that it's a relevant thing
12 now.

13 Okay. Oh, yeah. And then the last page, 12,
14 "What's the potential for acute or chronic noncarcinogenic
15 health effects. . .?" PAN might be better off there. Let's
16 see. It's acute. I have no idea about chronic effects of
17 PAN. But that might be where you again mention it, because
18 that is, again, a critical issue.

19 So, that's basically on the Executive Summary on
20 the exposure side. And I had a few other comments --

21 DR. DENTON: Dr. Pitts, just one other thing
22 before we move on. We did have a discussion of PAN,
23 you're right, in Part A, Page A-63.

24 CHAIRMAN PITTS: Oh, A-63.

25 DR. DENTON: So, we can bring that up within the

1 Executive Summary.

2 CHAIRMAN PITTS: Yeah. Here's PAN. You actually
3 have a reaction there. But there's no discussion of the
4 impact. That is the most -- the thing that most bothers
5 me about acetaldehyde, that is forms PAN. Okay. That's
6 where I saw it. Okay. Fine.

7 I have some other comments on Part A, but I
8 think we can put -- in the interest of time and so forth,
9 I would certainly bring into Part A this question of the
10 potential ethanol fuels, and you've also got a very good
11 section in Part A talking about the fact that you have a
12 Phase 2 ARB gasoline coming in '96. That's in Part A.
13 Some of that might well occur -- you do mention it in the
14 Executive Summary, but it's important that you are
15 speciating these things now, and you do have some numbers
16 on these things. And there's a paper been published
17 by Schutzel (phonetic) and some of his coworkers in which
18 they discuss the impact of from going from regular
19 gasoline to reformulated fuels to Phase 2 fuel. And
20 that's the one you're talking about. And it might be
21 worth commenting on that or checking into what that might
22 be in terms of acetaldehyde levels.

23 But whatever else we have, I think we have to get
24 that in.

25 Are there any other items for discussion? Yeah,

1 Jim?

2 DR. SEIBER: They discuss the effects of alternate
3 fuel programs on page 5 of the Executive Summary. To me,
4 that's where it ought to be brought out that any switch
5 to ethanol could accentuate the acetaldehyde formation.
6 So, that seems like a logical place.

7 CHAIRMAN PITTS: That's a good place to put it,
8 right there, right.

9 DR. GLANTZ: I have a couple of things.

10 CHAIRMAN PITTS: You're on.

11 DR. GLANTZ: I had a couple of issues that I
12 came away not clear on. The first was the relative
13 importance of indoor versus outdoor exposure, because the
14 concentrations that were reported indoors were a lot of
15 higher. And I was wondering if you could clarify that.
16 And then a related question is the relative role of
17 manmade exposures versus naturally occurring exposures --
18 wildfires and things like that.

19 Because I came away not clear as to how much
20 of what's out there is out there because people put it
21 there and, hence, it can be somehow controlled. And how
22 much of the exposure that's out there is out there because
23 they have a fire in the Sierra or because it was
24 a naturally occurring compound in foods or something.

25 So, could you just clarify that for those -- the

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1 two related issues having to do with the total.

2 MS. MARTZ: Dr. Glantz, looking at the
3 preliminary data -- now, this does not have quality
4 assurance; so, we're not citing it. I want to make it
5 very, very clear about that. This is preliminary data.
6 We looked at 2588 data. It appears that such industries
7 such as cement manufacturers with kilns, cold fire
8 kilns, wood cogeneration plants, paper making -- paper
9 pulp, these are all industries -- well, two of them --
10 where water is involved, or liquid making a slurry, and
11 the water has to be driven, so a furnace or process is
12 used -- fuel combustion. And in the inventory, great
13 amounts of acetaldehyde were released from from those
14 processes.

15 So, through our preliminary work, some of those
16 items are appearing. Does that help?

17 DR. GLANTZ: Well, that's part of it.

18 MS. SHIROMA: Good afternoon. Perhaps in answer
19 to your question, Dr. Glantz, first of all, on the
20 indoor contribution versus outdoor contribution, Peggy
21 Jenkins isn't here, but, as you know, one of the things
22 that she constantly preaches to us is the quality of the
23 data and, therefore, what can we actually put into the
24 report. So, Joan, you can clarify or, Linda, but the
25 information provided in the report -- albeit the data

1 appears high, but it was only so much as she was
2 comfortable in giving. She didn't feel comfortable in
3 giving a risk analysis, like we did for formaldehyde.

4 And then, the contribution of wildfires and
5 the activities of society, or whatever, in terms of
6 emissions, Joan, do we have some pie charts and things
7 that help clarify this in the report?

8 DR. DENTON: We do. In fact, 63 percent of the
9 stationary area source contribution was wildfires, and
10 the total direct contribution is about 40 to 60 percent
11 of the total acetaldehyde. So, we could maybe add some
12 kind of clarifying language to that.

13 DR. GLANTZ: Yeah. I think that these are real
14 important issues. I think several of the commenters in
15 Part C kind of got to this. I think it's important to --
16 in the Executive Summary and also in the Part A -- to
17 more clearly spell out, you know, where this stuff is
18 coming from, whether it's the indoor versus outdoor
19 issue, and also the naturally occurring versus manmade
20 occurrences. Because that really, I think, will have
21 major bearing on what kind of decisions people make in
22 terms of control measures. I thought that several people
23 raised that as an issue. And in reading the report, I
24 tried to get a good sense for that. Like it's not a good
25 thing to be in a smoky bar. I came away with that. And

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1 And it looks like the indoor concentrations
2 are higher than the outdoor, you know, by a factor of
3 two or three. But it wasn't even clear -- of the indoor
4 things, how much of that is there kind of naturally,
5 although most of that would be from smoking, or burning
6 wood, or something. But is that where people getting
7 most of their exposure, or is it because of ambient
8 exposures outdoors? And of the ambient exposures
9 outdoors, how much of that is something that we have
10 control over?

11 And I think the comments that Dr. Pitts is making
12 about the potential impact of ethanol fuels becomes very
13 important, because my reading of this was that -- I mean,
14 I didn't come away convinced that this is a huge problem
15 in terms of outdoor sources, manmade outdoo- sources. And
16 if we were to produce a report that kind of left that
17 impression, yes, it's a toxic, but, you know, there's not
18 a huge amount of it being generated in ways people can
19 control, I mean, that would lead the ARB to one set of
20 recommendations. But the way people are coming along and
21 saying we're going to put ethanol in everything, and
22 all of a sudden it's going to become a big problem. I
23 think it would be nice to highlight that fact. And that's
24 an area that I thought the report was weak in answering
25 those questions, for me at least. Did I miss something?

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1 DR. SEIBER: I think you're right on. Where it
2 comes in the Executive Summary, it says there'll be
3 288 acetaldehyde induced potential cancer cases, it
4 might be nice to know if 260 of those would be produced
5 anyway from acetaldehyde that's already out there.

6 In other words, what are we adding to the burden
7 of natural conditions by emitting acetaldehyde from
8 controllable sources? And I don't know the answer, and I
9 don't suppose you do either. But that would be a nice
10 number to know.

11 DR. GLANTZ: Yeah. I mean it's a little bit like
12 the issue that came up with 1,3-butadiene, I think, where
13 one of the public commenters -- I think it was GM -- came
14 in and pointed out that a lot of the exposure was from
15 second-hand smoke.

16 And if you look at it in that context, you know,
17 it makes the controllable outdoor effects look different.
18 So, I'd like to see some sort of pie chart or something
19 as to where that's coming from and how that might change
20 if there's a major change in the fuel mixture.

21 I mean the auto people were making a big deal
22 in the comments, and I just skimmed through the ones that
23 were here, that the mixture of fuels is changing and the
24 cars are changing in the way it will be reducing emissions.
25 And if that's the case, that's wonderful. But from what

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1 we've heard here, there could be a reversal of that
2 trend because of change in the mixture of the fuels.
3 That's another real important point, I think.

4 DR. DENTON: Dr. Glantz, I think those are
5 excellent points. We would kind of take this back and
6 sort of relook at the data. And keeping in mind, of
7 course, that acetaldehyde is a combustion-related product
8 from all different types of combustion, as well as
9 photochemically generated, and see if we couldn't
10 clarify in the report itself and, if possible, develop a
11 kind of pie chart as you suggest.

12 DR. GLANTZ: The other question I have, and I
13 don't know if it's appropriate now or if it would be
14 better to wait until the Part B discussion, is this issue
15 of acetaldehyde which is in foods and acetaldehyde which
16 is part of the normal metabolic process, and how that
17 colors the analysis.

18 Would that be better in the second part of the
19 discussion?

20 DR. DENTON: Yes. I think George is going to
21 address that. We do have a little bit of a discussion of
22 food and --

23 DR. GLANTZ: Why is George looking -- rolling his
24 eyes around? For the record.

25 (Laughter.)

1 DR. BECKER: I would also make that same
2 recommendation, Chuck. One of the things -- we have this
3 lead subgroup, and one of the comments was that, well, we
4 get the lead from the soil and we get lead from paint
5 and water sources. And you're looking at a minute
6 portion of the total lead burden that comes from air.
7 And so, however, the other side to that is, when you're
8 doing risk assessment, it's very hard to bring that in.
9 That's sort of a secondary perspective.

10 So, in order to make the document complete, I'd
11 still recommend that you say where the sources are for
12 the acetaldehyde, just like we said in the document for
13 lead, where the lead is coming from. Because in that
14 circumstance, the contribution from the air in specific
15 areas, especially might be significant for children.
16 So, that question is going to come up when it comes to the
17 control phase.

18 MS. SHIROMA: As I hear your reaction to the
19 report, which is good for us to hear, because you're
20 giving a fresh perspective to this, it sounds like, on
21 one hand, we have the information contained in the report,
22 but what we need to do is show clearly upfront in the
23 Executive Summary right away what are the contributions of
24 acetaldehyde, from where, and how is that all put into
25 context -- whether it's indoor or outdoor, wildfires, or

1 motor vehicle combustion, or secondary, or what have
2 you. So, it sounds like, we can present that in a more
3 concise way right up there in the Executive Summary.

4 I gather that's basically what you're telling
5 us to do.

6 DR. SEIBER: I think that's good. But you've
7 also got to point out the big unknowns. How much is
8 emitted from vegetation? I'll bet, you know, it won't be
9 in your pie chart, because you don't have any data on it.

10 So, we've got to at least recognize there can be
11 some other sources that haven't been measured.

12 MS. SHIROMA: So, you're saying, also clarify
13 what we don't know.

14 DR. SEIBER: Yes. Right.

15 CHAIRMAN PITTS: Let's think about that.

16 (Laughter.)

17 Are there other questions? Let me just wind up,
18 then, briefly by going along with -- it just occurred to
19 me also that this whole question is extremely important to
20 the public and the Air Resources Board, and the whole
21 idea of the ozone reactivity of emissions, exhaust
22 emissions. It's the law now since September, 1990. We're
23 now looking at emissions in terms of milligrams of ozone
24 per mile, not grams of hydrocarbons or VOCs. I think that
25 has a lot of problems with it, but it's also a great idea.

1 There's a lot going for it. It's under a lawsuit. There's
2 a lawsuit now by WSPA saying you can't do that, because
3 there's too many uncertainties in how we calculate ozone
4 reactivity, the VOCs. We used to call them hydrocarbons,
5 Gary. But now they use the term reactive organic gas,
6 which is even better, because some of the VOCs are
7 volatile organic compounds, but they don't react here;
8 they react in the stratosphere.

9 So, to clarify that, you say reactive organic
10 gas. Okay?

11 Now, along that line, in addition to ethanol,
12 maybe Don Ames knows -- I don't know about this. But
13 I have a hunch that in, for example, certain parts of
14 California, they mandated an increase in oxygenated
15 fuels in the wintertime to lower the CO levels. Now, I'm
16 not sure, but it was either methyl tert butyl ether or
17 ethyl tert butyl ether, and I'm not sure which.

18 DR. DENTON: Methyl.

19 CHAIRMAN PITTS: Methyl. But they're also talking
20 about using ethyl, because ethyl comes from alcohol.
21 And ethyl alcohol "ain't" going to be taxed. Excuse me,
22 change that to "isn't" going to be, won't you?

23 (Laughter.)

24 This is very important. And if you don't think
25 this is what drives society -- I mean, it isn't being taxed.

1 This is big time.

2 So, I wish you'd find out whether ethyl T butyl
3 ether may not be a source in the atmosphere. And it's
4 being used in other parts of the country, ethyl is being
5 used. And you should very much look into that and see
6 if that isn't another potential source.

7 The irony is, that was used to lower CO
8 levels, the idea of adding the oxygenated fuels. But,
9 boy, you're going to boost up the VOCs and potential
10 reactivities, and so, you may be producing ozone. It's
11 an irony.

12 Okay. That's fine. Are there any other
13 comments? Now, how is this going to get back to us?
14 There's going to be, it seems to me, some major changes
15 in the Executive Summary along the lines that have been
16 discussed by most of us here. Is there some way that
17 the draft could be made, and we could say, "subject to
18 approval of a revised Executive Summary"?

19 How would you like to do this? Do, you out there?

20 MS. SHIROMA: Don was saying that perhaps you
21 could review George's part of the presentation of Part B,
22 and then decide then. What we've done in the past in this
23 kind of situation, we would like to have some
24 clarification and so forth, is that we've worked with
25 the leadpersons or a subcommittee to go through the actual

1 language changes and then, upon that, we've gone ahead
2 and sent out a revised copy as more of an informational
3 kind of thing. Unless there was something seriously
4 deficient, it would need to come back to you. But for
5 clarification purposes, we'd work with a subcommittee
6 and then send out a new report to the mailing list.

7 CHAIRMAN PITTS: Yeah, that sounds fine.
8 I have no problem with that. Maybe Jim, as the exposure
9 guy, and myself could work with you and look at that. And
10 I think it'll all come out fine. If the Panel would agree
11 with that on Part A, then, I think Jim and I will
12 volunteer .

13 MS. SHIROMA: Sounds fine.

14 CHAIRMAN PITTS: Okay. That's fine. And now --
15 all right. Thanks very much. And now, Dr. Alexeeff,
16 we're now in Part B.

17 DR. ALEXEEFF: Good afternoon. My name is
18 George Alexeeff. I'm with the Office of Environmental
19 Health Hazard Assessment in Cal-EPA, and with me is
20 Dr. Jim Collins, the lead author for the acetaldehyde
21 report, Part B.

22 I'll make the presentation and Dr. Collins will
23 answer all the questions.

24 (Laughter.)

25 So, a fine division of labor here. Okay. We

1 conducted a review of the toxicological effects of
2 acetaldehyde and presented them in Part B of the ARB
3 document.

4 I'll briefly summarize what we think are the two
5 key aspects of , the reference concentration and the
6 cancer risk assessment.

7 Acetaldehyde vapor is an irritant to the eyes,
8 skin, and respiratory tract following either acute or
9 chronic exposure. In our document, we did not derive
10 a reference concentration for acute exposure, but we did
11 suggest one for chronic exposure. And this will be
12 essentially the first one that we've presented to the
13 Panel in a more formal manner, although we did present
14 a reference level for perchloroethylene as well.

15 The reference concentration was derived actually
16 by US EPA and is discussed in their IRIS database. I
17 have the calculation. Would you like me to go through it
18 on this slide? Would that be helpful? It's the first
19 slide. It's on the handout.

20 The way the process works for the RfC has many
21 similarities to the cancer risk assessment. Well, the
22 first is to identify the study. In this case, the study
23 used, as indicated in the document, is Appelman, and
24 that was an inhalation study with rats, exposing them daily
25 for four weeks to various concentration levels. The level

1 up there under the NOAEL -- no observed adverse effect
2 level -- was one of the concentrations at which no effects
3 were found.

4 Then that level is adjusted to an average 24-hour
5 exposure level. And then the next adjustment labeled
6 HEC -- that stands for human equivalent concentration.
7 And what you see there is an adjustment for the extra-
8 thoracic region. It's similar to our surface area type
9 of adjustment, but it's focused more just on that region
10 for a gas. And so, the human equivalent concentration
11 was 8.7 milligrams per cubic meter.

12 DR. FRIEDMAN: Could you explain what those
13 abbreviations stand for? I don't really understand.

14 DR. ALEXEEFF: Well, the first one is simply
15 the ventilation in the animal -- MVa is ventilation in
16 the animal, Sa is the surface area for that region.
17 And --

18 DR. FRIEDMAN: By extrathoracic you mean the
19 outside of the chest or everything else but the chest?

20 DR. ALEXEEFF: Everything else but the chest.
21 Because the effect for acetaldehyde for both carcinogenicity
22 and for noncancer effects were in the upper respiratory
23 tract.

24 DR. FRIEDMAN: Oh, you're talking about the upper.
25 respiratory tract.

1 DR. ALEXEEFF: Yeah. And then there is an
2 additional uncertainty factor added; in this case, it's
3 1,000.

4 DR. FRIEDMAN: I'm sorry to interrupt you, but
5 I just don't understand. Could you go through what those
6 abbreviations. What is the A and the H? Is that the
7 animal and the human? Is that what that stands for?

8 DR. ALEXEEFF: Yes, I'm sorry. Yeah, the first
9 one is the ventilation -- this would be a daily
10 ventilation rate for the rat in this case, and the other
11 one -- and then Sa would be the area, the surface area
12 in the upper respiratory tract for the rat. And then,
13 the bottom one is the ventilation -- the daily ventilation
14 rate for human in cubic meters per day, and then the
15 surface area for the human in the upper respiratory tract.
16 And the US EPA has developed a number of standard
17 calculation procedures for their reference concentrations,
18 and depending upon the area of impact and the type of
19 chemical involved, whether it's a vapor or a particulate.

20 DR. SEIBER: You want us to ask questions
21 later?

22 DR. ALEXEEFF: Whatever you --

23 CHAIRMAN PITTS: It's more effective if it's
24 done during the course of the discussion.

25 DR. SEIBER: Well, here's an NOAEL of 273

1 milligrams per cubic meter, and we're down to nine
2 micrograms per cubic meter. That's a thousandfold --
3 that's a big leap there. That first one says no adverse
4 effect level is 273 milligrams per cubic meter. And
5 then we're going to work with the number 9 micrograms per
6 cubic meter. Is a thousandfold safety factor, is that
7 standard in all their calculations?

8 DR. ALEXEEFF: Well, I can explain the source
9 of a thousandfold. It is a standard procedure, but it's
10 not necessarily -- depending on -- the uncertainty factor
11 is a reflection of -- in many parts of the quality of the
12 data or the uncertainty of the data. The more
13 "uncertainty" it is, the larger the uncertainty factor.

14 And, for example, if this was a human study, a
15 human chronic study, the safety factor may only be 10.
16 But since we're dealing with an animal study, the standard
17 procedures add a safety of 10 from an animal to
18 a human conversion. And then to reflect the variability
19 in the human population, another tenfold factor is used.
20 So, the hundred is probably the more standard number that
21 is used for the calculation. And this is the standard
22 values that are used in calculation of acceptable daily
23 intakes for, you know, for residues in food and that sort
24 of thing. And then, just to answer the question about
25 the thousandfold, the last factor of 10 comes into play

1 because this is for a chronic level, and it was only a
2 four-week study.

3 So, there's a factor of adjusting from a sub-
4 chronic study to a chronic study of 10.

5 DR. GLANTZ: Just to understand. The first thing
6 is to adjust for the fact that they only were exposed
7 six hours a day, five days a week.

8 DR. ALEXEEFF: Correct.

9 DR. GLANTZ: And so, you're saying if you were
10 to spread out the same integrated dose, and then the next
11 line is adjusting for the interspecies differences,
12 adjusting it for ventilation rate, body surface area?

13 DR. ALEXEEFF: Correct.

14 DR. GLANTZ: And then --

15 DR. COLLINS: Not body surface area, but
16 relative surface areas of the extrathoracic region. That's
17 what those areas are. They're not bodies.

18 DR. GLANTZ: Would you tell me again, what's the
19 extrathoracic region?

20 DR. ALEXEEFF: Upper respiratory tract.

21 DR. GLANTZ: Okay. And then, and then, what's
22 the logic for -- you went through these three factors of
23 10. Why did people select 10? Why didn't you pick pi
24 or some other --

25 (Laughter.)

1 DR. ALEXEEFF: Well, that's always a good
2 question.

3 DR. COLLINS: The minority wants to select pi.

4 (Laughter.)

5 DR. GLANTZ: But one of them, there was a factor
6 of three somewhere in something that I read. Why didn't
7 you use 10 there?

8 DR. ALEXEEFF: Well, there is, you know -- the
9 choice of 10 probably, you know, dates back to the original
10 National Academy of Sciences water documents, developing
11 the daily intakes -- acceptable daily intakes of
12 pesticides in water or contaminants in water, not just
13 pesticides.

14 And since then, US EPA has done a lot of
15 evaluation of available data to see how well the factor of
16 10 gets into reality. And so, the original choice was
17 probably based upon a good scientific judgment by members
18 of the NAS committee.

19 But since then, there has been a number of
20 articles published by -- primarily by US EPA staff, which
21 justify the factors of 10 by indicating the variability
22 that -- for studies where we know comparisons, either
23 between species or between animals and humans, what is
24 the distribution between the ratios -- and so, the factor
25 of 10 seems to fall in, not in the middle, but towards the

1 upper range of it. It's not the 95 percent confidence,
2 it's more like 60 or 70 percent of the distribution.

3 So, it's -- if we were to have actual factor,
4 you know, the numbers would vary if we knew what the
5 actual number is.

6 So, this is a -- you know, this is their
7 standard default number. The value 3 is actually an
8 additional factor in addition to this, which is called
9 their modifying factor. And that's if -- depending upon
10 the -- how they sense the overall quality of the data.

11 So, the highest uncertainty factor currently that
12 is applied is 3,000. And there are some previous
13 numbers -- the 3,000 decision is a couple years old.

14 But there probably are some older values where
15 10,000-fold factors are possible, depending upon the data.

16 DR. GLANTZ: And then how is this 9 milligrams (sic)
17 per micrograms per cubic meter number going to be used?

18 DR. ALEXEEFF: Okay. Well, the way this would be
19 used from the air standpoint, this would be, by our
20 standards, considered a chronic reference exposure level.
21 That is to say, once -- well, primarily this would be
22 used in the hot spots program, evaluation of facility
23 emissions. And so, the emissions of a facility would be
24 compared to this 9 micrograms per cubic meter level. And
25 if it were above that level, okay, then there would have --

1 well, it isn't decided what would happen if it was above
2 that that level. But from our perspective, above that
3 level, then there should be some consideration as to
4 what impacts might occur. You know, that's kind of an
5 overall interpretation. If any concentration is above
6 its reference level, we in OEHHA would suggest additional
7 valuation of what was the uncertainty factor involved in
8 the reference concentration to see if there is an impact
9 on this.

10 In general, for the various reference levels that
11 we've seen in our hot spots program, for acetaldehyde,
12 we've looked at 172 facilities so far in the risk
13 assessments we've reviewed. Some of the data that Linda
14 Martz was referring to were facilities that have not been
15 QA/QC'd.

16 But we've looked at their risk assessments and
17 of those, approximately 20 emit acetaldehyde. And the
18 highest that one of those facilities comes to this level
19 is one-one hundredth of that. And most of them are
20 thousandths, you know, much, much lower.

21 So, in terms of how it's actually going to be
22 used, the idea is that this would be sort of a -- you
23 know, a checkpoint. If it's above this level, you know,
24 there should be some looking at what the potential health
25 effect might be, in general, for reference level.

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1 It's primary use is, if it's below this level,
2 the impact should not be considered as -- it should be
3 considered a negligible impact. It's more of a de minimus
4 level or, you know, if we were to consider that the
5 one in a million risk as, you know, being a non -- below
6 that a nonsignificant risk would be similar to that (sic).
7 So, it's mostly useful -- with all the uncertainty
8 above -- it's mostly useful as if your exposure's below
9 that, we don't expect any health impact. And there is
10 a lot of concern from those -- from industry in the risk
11 management considerations as to what happens if you're
12 above that level. There's a lot of discussion -- ARB,
13 the air districts, CAPCOA, and OEHHA -- as to how to
14 best deal with what happens when it's above.

15 We do have, like one facility for reference
16 concentration for lead, which is the highest one, which
17 is about ninety-fold above the reference concentration.
18 And so, under that circumstance, you know, we'd start
19 getting concerned if it's, you know, we would want to
20 look at it much more carefully.

21 So, we had -- but for acetaldehyde, in particular,
22 we don't know of any facility that that's even a hundredth
23 of this level.

24 DR. SEIBER: So, George, do I take this to mean
25 that this number is not used in the risk assessment that

1 follows?

2 DR. ALEXEEFF: This number is part of the risk
3 assessment. This is for a noncancer impact, what would the
4 level be. That's what this number is telling us.

5 And this is something that we hope to -- well,
6 we are planning on bringing to the committee under --
7 we'll discuss later -- under our Calderon SB 1731 process.
8 In the months to come, we'll be bringing many numbers of
9 this gendre, many of which are not carcinogens. In this
10 case, probably the carcinogenic risk, if there was some
11 impact, the carcinogenic risk would have much more weight
12 than -- I would think -- than this thing.

13 But for those chemicals for which -- that are not
14 carcinogenic, you know, they could play a roll for
15 certain situations.

16 DR. FRIEDMAN: Do I take it then that the American
17 Conference of Governmental and Industrial Hygienists, in
18 allowing levels in this range, don't consider
19 carcinogenic effects at all when they set these standards?

20 DR. ALEXEEFF: Generally, they have not
21 considered -- they don't consider for acetaldehyde.
22 There are a few chemicals that they've considered, but
23 that's very few. Usually, those are the ones that we
24 consider there's sufficient evidence for human
25 carcinogenicity.

1 DR. FRIEDMAN: Like benzene or something like that?

2 DR. ALEXEEFF: Right. But even so, I think even
3 for benzene -- well, I know they've just updated their
4 values in this past year, so I can't tell you exactly.
5 But in the past, they haven't been much involved in the
6 risk assessment, cancer risk assessment process. They
7 usually just use it on a qualitative basis for
8 additional justification for lowering the standard to
9 whatever's feasible, technically feasible.

10 In reference to this, there was -- one of the
11 commenters from the Bakers Association found that there
12 was an inconsistency between the summary and our document.
13 And so, we will correct it. This is the correct value,
14 9, which is used in the document. The summary had 20.
15 What had happened, in the process, while our document was
16 going out for comment, the calculation procedure had
17 changed. So, and that was discussed at our workshop, that
18 the number was different.

19 And we just, unfortunately, forgot to change it
20 in the Executive Summary. So, we'll have to make that
21 correction in the next version.

22 DR. BECKER: Aren't there a few papers that have
23 looked -- aren't there a few papers where EPA has attempted
24 to look back over whether that -- the 10 times 10 times 10
25 is health protective or not? And empirically, that number --

1 and I've talked to some people who worked on the
2 original -- that was quite offhand; it was just a
3 guesstimate. But, empirically, when they've looked back
4 over the process and where there is information, that
5 number is health protective. So, it was really -- at
6 the beginning, it was very soft. But, in fact, I saw a
7 draft for a journal article that someone is writing,
8 looking back over that number, and it turns out to be a
9 pretty good guesstimate from a health protective point
10 of view.

11 So, the erring on the side of that error (sic)
12 is probably a good one.

13 DR. ALEXEEFF: Yeah. That's what I was referring
14 to. The US EPA has done several articles where they're
15 trying to look back and see if this process has worked.

16 And so, anyway, this is generally the process
17 used for noncancer types of evaluation.

18 Okay. Now, in terms of the carcinogenic risk
19 assessment evaluation, on the next slide, the
20 classification, as Dr. Pitts noted, there was -- the
21 information for IARC was not indicated in that section.
22 I'm referring to the summary. And also, again, the
23 American Bakers Association indicated that there was some
24 inconsistency in the wording as well between the staff
25 report and the summary. So, part of it has to do with,

1 I believe, the confusion of 2B and B2, and them meaning
2 probable versus possible.

3 So, in any case, as indicated on this slide
4 here, both the US EPA and IARC consider there's
5 sufficient animal data for carcinogenicity and, at the
6 same time, the human data is inadequate. Both their
7 terminology for rating it is slightly different. The
8 US EPA considers it a probably human carcinogen and IARC
9 considers it a possible.

10 DR. BECKER: Those were my questions in reviewing
11 this. I couldn't see from the document whether there was
12 a fundamental scientific difference of opinion about the
13 human data, because the Bakers Association critiqued
14 quite heavily the 1975 paper.

15 But are there no other papers that have looked
16 at human exposures? Is the difference based upon how
17 they're interpreting the human data, or is it something
18 else?

19 DR. ALEXEEFF: The difference, I believe --
20 I believe Dr. Zeise is probably our best expert -- our best
21 expert on classification schemes, and maybe she can
22 correct me if I make a mistake. I think it simply has to
23 do with the way they constructed their classification
24 schemes.

25 DR. BECKER: I mean, you can see that both of

1 them regard the human data as inadequate. Given the
2 animal data, one will call it probable and the other
3 will call it possible.

4 DR. GLANTZ: I guess the question is: Is the
5 EPA calling it probably the same as IARC calling it
6 possible?

7 CHAIRMAN PITTS: IARC has a probable category.
8 IARC 2A is probable. And that's why the fuss about
9 diesel exhaust. That's been put into 2A, and so it has --

10 DR. ALEXEEFF: For formaldehyde, which we
11 reviewed, that was a probable in both classifications,
12 and the human data were limited. So, in that case, IARC
13 would bump it up, but EPA would still consider it
14 probable.

15 DR. BECKER: Well, I think, if we're confused
16 by this, I think the people reading this are going to be
17 confused by it. And there needs to be some statement
18 on this -- is this semantic? Is this a semantic issue?

19 DR. ALEXEEFF: I believe it's a semantic issue.

20 DR. BECKER: Then if it is, then we should say so.
21 If it's a substantive scientific issue --

22 DR. GLANTZ: I thought you just it wasn't
23 semantic.

24 CHAIRMAN PITTS: I'm not sure it is semantic.
25 There's a big difference between if something's possible

1 and probable. It would seem to me, if they both went
2 through the same evaluation, the IARC team and the EPA
3 team, they have come out with different results.

4 DR. ALEXEEFF: If you look back on what leads them
5 to their final summary, they both consider the animal
6 data to be sufficient for carcinogenicity and the human
7 data to be inadequate. And I think that's the way to
8 look at it. There's no human information, but there is
9 sufficient animal information. Now, how one calls
10 that, in previous documents when we've run up into this --
11 we've run up to this before.

12 CHAIRMAN PITTS: Methylene chloride.

13 DR. ALEXEEFF: We have always called it a
14 potential human carcinogen just because it started getting
15 very confusing as to which term should be adopted.

16 So, that's why I think it's better to go to
17 what is the source information. So, that's what I thought
18 we would do. We'd clarify in these documents what the
19 basis of the information is and clearly indicate the
20 difference in their classification schemes.

21 CHAIRMAN PITTS: George, can't you just put then
22 somewhere in here -- an appendix or -- here's the IARC
23 classification: 1, human carcinogen, and 2A is this, then
24 put in a compansion box the EPA's version of what they're
25 doing, and that sort.

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1 DR. ALEXEEF: I could provide that.

2 DR. GLANTZ: So, the EPA is more convinced that
3 this is a carcinogen -- human carcinogen than IARC: is
4 that a true statement?

5 DR. FRIEDMAN: Well, they used the word
6 "probable." That doesn't mean they're more convinced.
7 Given what the evidence is, they call it probably and
8 IARC calls it possible. I don't think it needs to be
9 controversial.

10 CHAIRMAN PITTS: Define it that way.

11 DR. ALEXEEFF: If the data for -- if the animal
12 data were limited, then, usually the classifications
13 that data are inadequate, limited, insufficient -- both
14 groups use that terminology, fortunately.

15 if the animal data were limited, then US EPA
16 would call it a possible human carcinogen.

17 So, I guess one way of saying it is that IARC
18 might be more stringent on what it might classify as a
19 probable human carcinogen. US EPA bumps more things into
20 that category.

21 DR. BECKER: I think the problem is that when the
22 word "probable" is used, especially in torts, man-caused,
23 then that usually means you're 51 percent certain. And
24 that carries that burden, which is a legal issue not a
25 scientific issue.

1 Whereas, "possible" is anything is possible.
2 So, the end result is that probable carries more weight.
3 So, when there's a tort, then probable is much more
4 significant than possible.

5 DR. ALEXEEFF: Yeah. So, for IARC, for it to
6 come up to the probable level, there has to be at least
7 human data; otherwise, it won't be a probable. But US EPA
8 calls them a probable if they think the animal data is
9 strong enough.

10 Okay.

11 CHAIRMAN PITTS: Excuse me. I take it then that
12 you will clarify, to the degree possible, the discussion
13 we've had here, and then put that in the document upfront.

14 DR. ALEXEEFF: Would you like it in the
15 Executive Summary?

16 CHAIRMAN PITTS: I think so. In the Executive
17 Summary, you're going to put IARC in, and it's possible
18 and probable, so put in the definitions put in by the
19 two groups.

20 DR. ALEXEEFF: Fine. We'll do that.

21 DR. GLANTZ: And if I could just beat this dead
22 horse one more time. A clearer way to do that, because we
23 don't want the Executive Summary to turn into Part D of
24 the document, the way you might say it is that you could
25 say, both the EPA -- basically what you said here -- and

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1 IARC say that there is sufficient animal data and
2 insufficient human data, and then say, this led IARC to
3 say it was possible and EPA to say it was probable.

4 That would do it with a minimum level of words.

5 DR. FRIEDMAN: By their classification schemes.

6 CHAIRMAN PITTS: By their classification schemes
7 seen in Appendix D. Then you can have a D.

8 DR. GLANTZ: Right. Okay.

9 DR. ALEXEEFF: Okay. Also, just to note that
10 acetaldehyde was listed as a chemical known to the State
11 to cause cancer under Proposition 65. It was listed in
12 1988.

13 Now, to calculate the cancer risk, there are data
14 on male and female rat nasal carcinomas. So, acetaldehyde
15 is acting similarly to formaldehyde. And if you look at
16 this particular slide here, it gives the dose levels and
17 the response rate, so you can see the nominal
18 concentrations, measured concentrations, and then, again,
19 an adjustment for continuous exposure. This is similar
20 to what we looked at for the other continuous exposure
21 adjustment. Now, it's important to note, this particular
22 study exposed -- for the animals listed here -- exposed the
23 animals for 28 weeks.

24 DR. BYUS: Months.

25 DR. ALEXEEFF: 28 months, excuse me. Just to make

1 sure everybody's awake here.

2 (Laughter.)

3 And it's more typical to have a 24-month
4 exposure. So, it is longer than most exposures. And
5 you can see the incidence rate for males and females.
6 You can see that the males appear to be more sensitive
7 than the females in responding to acetaldehyde, a
8 slightly increased incidence rate. And the calculated
9 risk level would be higher for the males.

10 Now, there was a third dose in the study, which
11 was 3,000 parts per million. But partway through the
12 study, animals began to die and exhibit toxicity. So, the
13 concentration was adjusted to about a thousand parts per
14 million. And as a result of those changes and the
15 effects in the animals, we didn't use that exposure level
16 for the calculation.

17 Now, on the next slide, it indicates the risk
18 calculations we used. And this is similar to what we did
19 for formaldehy, except it's much more simplified, because
20 there's less and fewer additional factors involved. But,
21 again, we had three different scaling factors, scaling
22 procedures. The first one is -- assumes a part per billion
23 equivalent between species; the second one is our standard
24 scaling surface area correction procedure, and then the
25 third one is our contact scaling. And that's more of a

1 volume area of the lung surface.

2 Okay. And so, it was calculated the same
3 way as in our formaldehyde document. These values here
4 represent the range of upper bound risk that we used in
5 our document.

6 We also calculated the maximum likelihood
7 estimate, which for the males is about 200-fold lower
8 than any of those numbers,

9 DR. GLANTZ: George, can you go through the
10 logic of these three different scaling factors in terms
11 of the assumptions about the biology, what's going on?

12 DR. ALEXEEFF: Well, the first one assumes that,
13 you know, a part per billion for a rat is similar to a
14 part per billion for a human. So, it assumes that the
15 concentration that the two different species are breathing
16 is the only determining factor. So, as long as they're
17 breathing the same concentration, there's no adjustment.

18 So, the second one is a surface area scaling,
19 which is surface area of the total body surface area,
20 which is our standard procedure in using cancer risk
21 assessment.

22 DR. GLANTZ: That's just a body surface area.
23 You don't have any lifetime or anything like that in
24 there?

25 DR. ALEXEEFF: No.

1 DR. FRIEDMAN: Well, the human body surface is
2 so much huger than the rate, how can you just come up with
3 a one-and-a-half times difference?

4 DR. ALEXEEFF: It's dose per surface area factor.

5 DR. GLANTZ: The dose effect is the same, isn't
6 it? I mean, shouldn't the second column be -- you know,
7 the point Gary's making is that humans are much bigger
8 than rates.

9 DR. BECKER: But the rats have a faster
10 respiratory rate, so the dose, you know, it's --

11 DR. ALEXEEFF: It has to do with the respiratory
12 rate, but it's the respiratory rate plus the area
13 involved --

14 DR. BECKER: The animal's breathing more rapidly,
15 their lung surface is different, and the correction factor
16 that's thrown in is based on those factors.

17 DR. GLANTZ: So, this isn't really just based on
18 body surface area, then. It's based on sort of, one,
19 surface area, respiratory rate --

20 DR. ALEXEEFF: No, the middle one is body
21 surface area. And that's our standard for body surface
22 area.

23 DR. FRIEDMAN: Well, then, I have to repeat my
24 question. Why is it one and a half times bigger?

25 DR. ALEXEEFF: Because it also deals with the

1 ventilation rate.

2 DR. FRIEDMAN: Oh, okay.

3 DR. ALEXEEFF: So, it's dose per surface area of
4 the body.

5 Now, there's a fourth factor, which isn't on
6 here, which is commonly used -- particularly for
7 noninhalation -- is dose per weight, the body weight
8 factors.

9 This one is dose per surface area. So, the
10 third procedure -- that's contact -- is dose per surface
11 area of the lung. Okay? And while we had some comments
12 that they thought for acetaldehyde that might be, you know,
13 a useful procedure, we haven't felt that we validated
14 that calculation thoroughly enough to actually use it.

15 So, we're presenting it mostly for comparison
16 to provide some information on the uncertainty involved.
17 And this is something that, as we go through our updating
18 of the cancer guidelines, we hope to look at this issue
19 a little more thoroughly.

20 DR. GLANTZ: I just want to make absolutely sure
21 I understand this. So, the metabolic, it's concentration
22 times volume times respiratory rate divided by body
23 surface area.

24 DR. ALEXEEFF: No. That's not the actual
25 formula.

1 DR. GLANTZ: Pi is closer?

2 (Laughter.)

3 DR. COLLINS: If we express this as milligram,
4 kilogram day, and were showing it up there, there'd be
5 the difference of nearly sixfold based on the relative
6 body weights to to the one-third power.

7 It's just it's more obvious when it's per
8 milligram, kilogram day. When it's done for ppb, because
9 of the respiratory volume, you lose some of the big
10 factors. so it ended up only as a factor of 1.2.

11 DR. GLANTZ: Okay.

12 What page is it on?

13 DR. COLLINS: It's on page 9-7.

14 DR. FRIEDMAN: It really would be helpful to me
15 if you could take us through this equation.

16 DR. COLLINS: Well, it says on the next page.
17 "Equation 9 gives the following scaling factors: 1.5
18 for the 400 gram male rat." So that if you -- I don't
19 have those written out here, but --

20 DR. FRIEDMAN: Is Equation 9 the equivalent of
21 the metabolic? Is that the metabolic?

22 DR. COLLINS: That's correct.

23 DR. FRIEDMAN: So, could you just say what these
24 letters stand for?

25 DR. COLLINS: A is the portion of carcinogen

1 absorbed. So, if you assume they're the same in the
2 animal and human, then that cancels out. So, it's
3 basically the weight of the human over the weight of the
4 rat times .75 minus n, which is two-thirds -- the bodyweight
5 scaling factor, and Ch is one relative to the other,
6 so the weight of the human or the weight of the rat
7 to 0.75 minus two-thirds should give you 1.5 for a 400 gram
8 rat, so you multiply 1.5 by the original 3.2, and that's
9 where we got the 4.8.

10 DR. FRIEDMAN: And what is the C?

11 DR. ALEXEEFF: Concentration. The equivalent
12 concentration.

13 DR. FRIEDMAN: I see. For the rat versus the
14 human. Okay. Thank you.

15 DR. ALEXEEFF: The reason it's called metabolic --

16 DR. BYUS: That's what I was going to ask.

17 DR. ALEXEEFF: -- is because its derivation,
18 the original basis for this assumption had to do with
19 metabolic differences and differences in oxygenization
20 capacity. That was how it was originally derived way
21 back. So, that's the terminology. Okay.

22 So, the ARB requested us to suggest a best value
23 within this range. And for that we chose 4.8 times 10 to
24 the minus 6. So, that number was chosen because it
25 represents the metabolic conversion factor and also because

1 it uses males, and we felt that it was valid to choose
2 males in this case, since there seems to be a slight
3 species difference.

4 Now, our value of 4.8 compares to the US EPA
5 value of 2.2 times 10 to the minus 6. So, ours is
6 higher in this case.

7 And there's a couple of reasons for that. One
8 is that they follow the assumption of equivalent ppb
9 between species in this case, at least they did in their
10 1985 document, which is the basis for this.

11 Second of all, there was a companion study by
12 the same investigator that took some of the animals
13 to 28 months and other animals to 12 months, but it exposed
14 the animals for 12 months, but then observed them later
15 at 24 months. And the US EPA combined all of the results
16 together. So, it changes the number slightly.

17 And then, the other difference -- there were a
18 few animals that the US EPA considered in their
19 denominator for their exposure for which it wasn't clear
20 if they had been examined for nasal carcinomas. So, we
21 didn't consider those animals. So, that's the basis for
22 the differences in the numbers.

23 Now, this risk assessment goes back to more the
24 typical type of information that's available for cancer
25 risk assessment. The last few compounds we've had --

1 formaldehyde, we had a lot of dosimetric calculations.
2 We had binding rates. We had cell proliferation rates,
3 a lot of additional information.

4 For butadiene, we had five doses at much -- getting
5 much closer to the ambient level than this is. So, this
6 is a much broader range of extrapolation than this does.

7 And, for example, for perchloroethylene, before
8 that, we had all this pharmacokinetic information where we
9 could adjust it. So, this gets back to sort of the bare
10 bones kind of information that's more typical for most of
11 the compounds available for cancer risk assessment, where
12 you have a fairly high exposure regimen to the animals
13 and there's very little additional modifying information
14 that's available for adjustments to get -- have a sense
15 as to how close we are to humans.

16 So, there's a lot of uncertainties in how well
17 this applies to humans, the range of extrapolation, the,
18 you know, the general applicability of rats to humans in
19 this case.

20 In any case, based upon the finding of sufficient
21 carcinogenicity in animals, and the results of the risk
22 assessment, we feel that acetaldehyde may cause or
23 contribute to an increase in mortality or increase in
24 serious illness.

25 Now, we had some comments that we received. We

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1 did hold a workshop. And we discussed the health effects
2 at that point.

3 And Dr. Friedman was there. In addition to
4 the comments received prior to the wrokshop and the
5 discussions at the workshop, we've had two additional
6 letters that discuss human health that was mentioned by
7 the Air Board's staff.

8 One is from Russell of Chevron. And his comment --
9 here it is. His comment had to do with our use of the
10 95 percent upper confidence interval and the use of that
11 in our range of risk values as opposed to including the
12 maximum likelihood estimate in the range of risks.

13 Now, we do calculate the maximum likelihood
14 estimate into the report, but it's not considered part
15 of the range. And, in general, whenever we've reported
16 the range of risks in our documents, we've always referred
17 to -- this is the range of upper bound risks.

18 There have been a few exceptions where we only
19 had one upper bound risk. And ethylene oxide is one,
20 so we did report the range of the MLE to the upper bound
21 risk. Because we are required to report a range by
22 statute. In any case, we -- staff and we have had concerns
23 about using the maximum likelihood estimate. It has a
24 connotation of appearing to be a more accurate estimate
25 or an average estimate. We don't feel it really addresses

1 that kind of issue.

2 Dr. White indicates in his letter that he feels
3 that -- well, the implication is that it would be a more
4 a more accurate estimate of what the risk really is.
5 And I have this one slide which addresses one of our
6 concerns for the maximum likelihood estimate.

7 What we've done here is we are looking at the
8 sensitivity of the maximum likelihood estimate to slight
9 changes in what might have happened in the bioassay. You
10 see, the male tumor incidence that we use in our risk
11 assessment for best value of 1 in 49, 17/52, and 41 and
12 53. But we just said, well, what happens if we changed
13 that 17 and 52 by one or two animals, if there was a
14 misclassification or a reclassification.

15 And you can see about the third line down, and
16 17 and 52 calculation for the maximum likelihood estimate,
17 and you see there's about a 200-fold difference. Okay.

18 Well, if we go down and if only 16 animals
19 responded positively, the maximum likelihood estimate
20 would be zero. Whereas, the upper bound decreases slightly.
21 And then, if you go the other way, if there was an
22 additional classification, you can see how the maximum
23 likelihood estimate goes up to tenfold if just one more
24 animal was found to have cancer. And if there were three
25 more animals, you then see how the maximum likelihood

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1 estimate becomes very close to the upper confidence limit.

2 So, in part, it has to do with the formulas
3 that are used for this extrapolation. The maximum
4 likelihood estimate is very susceptible to the number of
5 animals in that lower dose region. And that's one of the
6 concerns we have in using it. We don't think it really
7 gives a more accurate risk estimate.

8 DR. FRIEDMAN: You're just saying it's much less
9 reliable.

10 DR. ALEXEEFF: Uh-huh.

11 DR. FRIEDMAN: But isn't it, quote, "nearer to
12 the truth"?

13 DR. ALEXEEFF: Well, we wouldn't say it's
14 necessarily nearer to the truth. What we think is that
15 it would be better -- well, we're talking now of future
16 guidelines development to come up with a procedure that
17 can calculate an average risk as well as an upper bound
18 risk. But we think that MLE does not fit that bill of the
19 average risk. And I don't know if Dr. Glantz has any
20 comments about MLEs in his experience, but -- and I'm not
21 a statistician. Dr. Zeise is here, who could answer that
22 kind of a question. But the way I understand it is that
23 the MLE represents the peak of the distribution curve. If
24 you look at the distribution of risk, the MLE represents
25 that peak point, where the 95 percent represents that

1 outer bound point.

2 So, the peak will shift a lot depending on that
3 that number. But that upper bound does not change that
4 much.

5 And so, we have concerns that if we were to use
6 the MLE, that we may underpredicting what the risk is,
7 because it is so highly variable.

8 DR. FRIEDMAN: You chose to go in the direction
9 of higher using the upper bounds; would the lower bound
10 have been just as reliable?

11 You chose to take it to move it up for health
12 protective reasons; is that --

13 DR. ALEXEEFF: Correct, yeah.

14 DR. FRIEDMAN: Is there a way you could perhaps
15 take the upper and lower and --

16 DR. ALEXEEFF: Well, that's another suggestion.
17 And I think that this is something that we have to really
18 think through with our cancer guideline development. Is
19 there a better way of expressing this kind of information
20 so that we can, you know, provide adequate public health
21 protection, address issues of uncertainty, and at the same
22 time, give a sense as to how -- when we get into
23 uncertainty, we get into all these formulas and
24 calculations. It would be nice to give some other way
25 of expressing how strongly or confidently do we feel about

1 these data in terms of what might be the actual case. And
2 I think it's something that is hard to do for just this
3 chemical, to choose the MLE. It's something I think
4 we need to put some great thought when we revise our
5 cancer guidelines to try to come up with some procedures.

6 I think that we think there are some out there,
7 this average calculation procedure that we've been looking
8 at. But we generally don't like to change the
9 calculation procedures from compound to compound, which
10 would be easy to do, because we keep getting, you know,
11 a little bit more information. But what happens, if we
12 were to do that, is it makes it difficult to consider
13 what are priority air pollutants and try to -- for the
14 risk managers to get a sense as to, is this one worse than
15 another?

16 So, this way, unless there clearly is some
17 exposure differences that we change or some of the other
18 pharmacokinetics -- if there's other information that
19 we -- that gives us more scientific information, then we
20 would incorporate that.

21 But, in this case, it's -- we don't have that kind
22 of information.

23 DR. BECKER: Let's see if anybody has any comment
24 on Part B.

25 DR. ALEXEEFF: I have one more. Yeah, it's

1 actually going to be a couple more minutes. It's another
2 submission from American Bakers Association.

3 And it's a rather lengthy document that was
4 submitted to ARB on May 5th. And I think it's unfortunate
5 that the organization didn't -- the Bakers Association
6 didn't try to get involved in the process earlier and
7 participate in our workshop, because a lot of these issues
8 they raised were discussed at our workshop, and were
9 issues also that we've discussed in formaldehyde.

10 So, some of our -- many of the issues are
11 similar to many other compounds.

12 CHAIRMAN PITTS: The court reporter needs a
13 five-minute break.

14 (Thereupon, a recess was taken.)

15 CHAIRMAN PITTS: Okay. We'll finish off Part B
16 here. And George is going to go ahead and give us a
17 condensed summary, discuss it in the Panel, then we will
18 vote on Part A, B, and the Executive Summary, and the
19 findings.

20 And the suggestion is that we have an option
21 of, in fact, approving it, subject to the fact that the
22 Executive Summary, the findings, and A and B will be
23 revised in accordance with our discussion. And that the
24 revised versions of these documents will come back to the
25 Panel with the original and then the marked version of

1 how it's been changed. And then the Panel can then
2 approve or disapprove at that stage. Okay? We'll approve
3 it. We won't say seriously deficient. But it's up to the
4 Panel to decide after this discussion. Do we feel it's
5 seriously deficient, or do we want to take that option. I'm
6 not making that decision for our Panel. I'm just saying
7 that's the course that we could use.

8 DR. GLANTZ: Well, I don't know quite what we're
9 going to call it, but I would feel more -- I think
10 there's enough issues that are problematic that I'd kind
11 of like to not say it's okay until we see another draft.

12 CHAIRMAN PITTS: What would you say? You want
13 it deferred? Defer a decision.

14 DR. FRIEDMAN: That would use a lot of time at
15 another meeting, and I wonder if we want to spend
16 another meeting on this.

17 DR. GLANTZ: Well, I don't know that we need to
18 spend another meeting, but I think that the issues that
19 are being raised are substantive enough to. I think we're
20 talking about more than just editorial, you know,
21 tinkering around. And it would be nice, before we
22 formally approved it, that we should see it. I don't think
23 it would require a whole big, long discussion.

24 But why don't we just--let's finish talking
25 about it first.

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1 DR. BYUS: That would be good.

2 CHAIRMAN PITTS: Fair enough. Let's go. You're
3 on, George.

4 DR. ALEXEEFF: I just wanted to comment on the
5 American Bakers Association comments. And, as part of the
6 process, we will have to respond to these in writing for
7 the record, which will go into the final document that
8 goes before the Board.

9 In any case, the first comment discusses the
10 difference in possible versus probable, and the confusion
11 in that. So, you have addressed that earlier, and
12 we'll correct that in the document.

13 And the second comment discusses the information
14 we know about the industrial exposures in humans; that
15 people have been exposed in workplaces, and that there
16 is not an observed incidence of cancer in humans in those
17 workplaces.

18 And I think we acknowledge that. The data is
19 inadequate on humans. One of the big issues is the
20 complication -- mixtures of exposures. But the comment
21 states that, based upon the occupational data, that
22 we should reconsider coming up with a potency slope for it.
23 The human data, as far as we can tell, it's inadequate,
24 and we can't say much more than that.

25 The next issue was also briefly brought up by

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1 the Panel and had to do with other exposure routes for
2 acetaldehyde. And this was also discussed at our
3 workshop. And the concept here is that there's --
4 acetadelhyde is present in the diet in a number of foods,
5 and it's a major product of metabolism following
6 alcohol consumption. And that, as a result of, you know,
7 the long human usage of these products, there doesn't
8 seem to be an association. That's one issue -- there
9 doesn't seem to be an association for cancer. At the
10 same time, there's fairly high levels in some of these
11 foodstuffs.

12 So, our assumption or our feeling is that for
13 inhalation exposure, it's a different issue than for
14 oral exposure. And we've looked at a number of compounds
15 where inhalation exposure is more sensitive than the oral
16 exposure.

17 And we feel that that may be the case here. So,
18 our recommendation is simply for an inhalation value
19 and not for an oral cancer value.

20 DR. GLANTZ: If I could just jump in there.
21 One of the commenters raised the issue of -- given there's
22 oral exposures and that there's naturally occurring
23 acetadelyde, and it's in foods, the model used -- the
24 Global 86 model -- wasn't really appropriate, or there
25 could be some problems with it. Because the way we've

1 usually seen that treated, it's usually been some totally
2 exogenous type compound. That struck me as a fairly
3 serious criticism. I mean, could you address that?

4 DR. ALEXEEFF: Well, actually, it's not that
5 unusual of a situation; even with the formaldehyde, that
6 was brought up as formaldehyde from metabolism, endogenous
7 metabolism.

8 And if you look back on some of our other
9 compounds, chromium, cadmium, those are in the diet
10 and naturally occurring metals. And generally, what
11 we've tried to do is separate the impact from oral from
12 inhalation, unless we can demonstrate that they're similar.
13 So, especially, since the impact here is on the upper
14 respiratory tract, we think something different can be
15 going on up here in the respiratory tract than if it was
16 distributed throughout the body.

17 If we were talking about kidney tumors or
18 something where it's a systemic tumor process away from
19 the site of entry, then I could see where the issue becomes
20 more relevant, because then there would be -- would have
21 to be some weighing between the two routes of exposure.

22 But I don't see it as that different from other
23 compounds that we've had. Those are the ones that come
24 immediately to mind. I think Dr. Becker will have -- when
25 we do lead, it'll be that issue. And Dr. Becker mentioned

1 there's always other sources. And it's important to
2 indicate those other sources.

3 DR. GLANTZ: I think that's a real good answer,
4 George. And I think that needs to be in the document.
5 I think you've answered the criticism very well. But in
6 reading through the comments, I mean, that struck me as
7 a very serious criticism, which you've just dealt with.

8 And that's another point that ought to be made
9 strongly and probably also -- and briefly -- in the
10 Executive Summary.

11 You're talking about tumors in the initial point
12 of contact rather than the systemic tumors. And I think
13 that's a very good point.

14 DR. ALEXEEFF: Okay. Now, the next issue they
15 bring up is similar to the issue we've had in
16 formaldehyde, and that is the potential in the animal
17 exposure, that there could be saturation of metabolic
18 processes for metabolism in the nasal epithelium, and
19 that, you know, it probably would be good to have some
20 sort of dosimetric correction. But, unfortunately, we don't
21 have any information for the correction. With
22 formaldehyde, we had what we call those DPX values
23 binding to the DNA, and we did correct for metabolism
24 problems and things like that. So, that is an issue
25 that's brought up. In this case, there just isn't that

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1 kind of information to make the adjustment. And also,
2 the issue brought up regarding cell proliferation,
3 that that could be another factor.

4 And that's true. But again, there's no
5 cell proliferation data for acetaldehyde for us to
6 make any correction.

7 So, the other issue is one that's again common
8 and has to do with the -- well, similar to formaldehyde.
9 It's the relevance of the nasal tumors in the rats
10 versus some human cancer incidence. And, generally,
11 we felt that unless there is some evidence that allows us
12 to pinpoint the concordance between animals and humans,
13 we are a little bit fuzzy about what the site would be in
14 humans. So, we're not predicting nasal cancers in
15 humans. We are predicting upper respiratory tract
16 cancers, or we're saying that's the target area of
17 concern.

18 So, a lot of the issues were the same thing with
19 formaldehyde, because there are some differences in the
20 nasal epithelium between rats and humans. But we don't
21 have enough -- there isn't enough information to really
22 flesh all that out and to come into some sort of a way
23 of coming up with a better dosimetric adjustment right now.

24 And then, their final comment has to do with
25 essentially what's been happening with this number once

1 it's identified and the implications for controls. And
2 I think that Dr. Denton mentioned that, you know, there's
3 a whole other process that goes on for the controls.

4 And now, we've also added -- that is, primarily,
5 it's the ARB's lead in developing risk management
6 guidelines for all the air districts for, you know,
7 considering controls and things like that. So, in terms
8 of identifying the number, that does not necessarily
9 lead to controls, particularly not from the ARB's
10 standpoint, because the controls are evaluated for
11 reasonableness and usefulness of controls for those
12 compounds.

13 So that, in a nutshell, summarizes their comments.
14 So that concludes my presentation.

15 CHAIRMAN PITTS: Thanks very much. I'll open it
16 to the Panel now. Gary, would you like to comment? We'll
17 go around the table.

18 DR. FRIEDMAN: I thought this was a fine
19 document. I don't think it's seriously deficient. I had
20 a few minor points to bring up. One thing that was not
21 clear to me, on page 1-1, you said, "At ambient
22 temperatures, acetaldehyde is a gas."

23 And then, two pages later, we see that it has a
24 boiling point of 20.6 degrees Centigrade.

25 So, I would think that a lot of the time, you

1 know, the temperature's colder than that in the
2 atmosphere and it would not be a gas. And I'm just
3 wondering, does it then turn into droplets, or is it
4 just like vapor that's in equilibrium? You know, could
5 just explain a little bit more about that?

6 DR. ALEXEEFF: Does the ARB have a good answer
7 for that one?

8 DR. DENTON: No.

9 DR. ALEXEEFF: Primarily, it's produced in the
10 combustion sources. So, it would be emitted certainly as
11 a gas from the sources that are generally hotter. But
12 my guess is that it probably would either adhere to
13 particulates or droplets -- becoming droplets. I'm not
14 sure what the environmental fate is.

15 DR. FRIEDMAN: I'd just be curious, because if
16 the boiling point is that high, I think -- let's see,
17 that would be about 68 degrees. A lot of the point it
18 would be under that boiling point.

19 CHAIRMAN PITTS: If you just poured some on the
20 table, it would evaporate. If you put it in a bottle and
21 put a stopper on it, it would come to equilibrium, the
22 equilibrium vapor pressure.

23 DR. FRIEDMAN: On page 9-4, there's just a little
24 typo in the middle of the page, that little paragraph
25 beginning with, "The model generated an upper 95 percent

1 confidence. . ." The fifth line of that paragraph should
2 have the word "considering," rather than "consider."

3 DR. ALEXEEFF: Right. Okay.

4 DR. FRIEDMAN: And I thought that on page 9-10,
5 the middle paragraph was really very good in terms of
6 all the questions that have come up at the workshop by
7 other questioners about the uncertainty, I thought
8 you really gave a nice description of that in that
9 paragraph. I'd like to commend you for that.

10 And I certainly -- as an epidemiologist, I
11 certainly agree that the one human study is inadequate,
12 and the animal study's certainly persuasive as far as
13 rats go.

14 And I think you've come to the only conclusion
15 you can, given the rules that you're operating under.
16 I must say that I'm not losing any sleep over acetaldehyde
17 causing cancer, you know, based on the weakness of the
18 evidence and the uncertainty of it and the apparent low
19 risk. But I think you've done what you've had to do.

20 DR. ALEXEEFF: Thank you.

21 DR. FRIEDMAN: So, that's all.

22 CHAIRMAN PITTS: Thank you.

23 DR. WITSCHI: Yes. One of the comments from
24 MVMA caught my attention. They took issue with the
25 extrapolating from a five-hour exposure to the 24-hour

1 exposure. And, unfortunately, I have nothing better to
2 offer. But I think your response you gave is not quite
3 correct either.

4 First of all, it's known from the ozone
5 literature that it makes a big difference that an exposure
6 is continuous or intermittent, even if the oral doses are
7 the same. So, I think they have a real point by saying
8 you cannot simply say that continuous exposure is
9 identical to intermittent exposure provided the cetane
10 product is the same. This is simply not true.

11 The other one in your response, the relationship
12 other than Haber's Law, has not been shown to hold for
13 carcinogenic response. I don't think that's true either.
14 I'm not too familiar with the radiation literature, but
15 I think dose rate, that you have to think about this
16 in terms of dose rate. It's a very important
17 determinant for carcinogenic response. And I think there's
18 even some evidence for chemical carcinogenesis way
19 back in the sixties in nitrosamines, again, where the dose
20 rate can be the driving factor as opposed to just overall
21 dose.

22 So, you may be right. I can't offer any
23 improvement of the procedure you had, but probably it's
24 faulty.

25 DR. ALEXEEFF: Uh-huh.

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1 CHAIRMAN PITTS: Stan?

2 DR. GLANTZ: I just had one other thing to add.
3 I had the same reaction Gary did about the paragraph on
4 page 9-10 about the uncertainty. I thought that was also
5 very well stated.

6 And I think that that's something you ought to
7 put in the Executive Summary and maybe even the findings,
8 the SRP findings, because everyone's always concerned
9 that we give a clear statement about the levels of
10 uncertainty. And I thought that was put very nicely.
11 It's the third paragraph, the range of risk values.

12 CHAIRMAN PITTS: Third paragraph, page 9-10?

13 DR. BYUS: It's partially in there.

14 DR. GLANTZ: Yeah, it's been a while since I
15 read the Executive Summary. Because as I got to the
16 end, I even put a mark next to it to demonstrate how
17 excellent it was.

18 CHAIRMAN PITTS: In the findings as well as in
19 the summary.

20 DR. BECKER: I have very mixed comments about --
21 I mean, it is impressive, because it's such a steep dose
22 response relationship in the inhalation studies in the
23 animals. So, that is impressive. But I do think you have
24 an obligation, because I think one of the things that you
25 said -- it's almost like the "Emperor Has No Clothes."

1 You drink grand quantities of C₂H₅OH, and it gets
2 converted to big time doses of acetaldehyde. And you said
3 it's not associated with cancer when, in fact, it's
4 quite well accepted that alcohol intake is associated
5 with human cancer, especially in the upper GI tract.

6 Except with this compound, I would have passed
7 on all the others, but I think there could be a very
8 strong argument. After all, if you look at Bruce Ames'
9 stuff, where he looks at the potency -- cancer potency
10 estimates, you'll see that C₂H₅OH is at the top of the
11 list, and it is being metabolized to acetaldehyde. So, if
12 you estimate the total number of grams consumed by
13 citizens in our society, you're talking about gallons
14 and two to three grams a day, certainly the risk estimates
15 at least deserve comment about the endogenous, because
16 the quantitative estimates of it. That's the argument
17 that Bruce makes when you look at that. So, once I've
18 said all that, I'm not sure what to do with it, because
19 there's been a lot of other people who thought about this.
20 And it's impressive about the contact carcinogenetic
21 nature of formaldehyde and acetaldehyde. And that is
22 impressive. But I only share that with you, and I would
23 only ask perhaps that you just address it and point out
24 the uncertainty of it. And I'm surprised at the -- if I
25 was critiquing this for the other side, I would have made

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1 more of an issue of acetaldehyde endogenous in this
2 particular comment. In the other ones, it was trivial.
3 Here, it's probably big time doses of --

4 DR. ALEXEEFF: Well, you know, alcohol
5 consumption is associated with carcinogenicity.

6 DR. BECKER: Right.

7 DR. ALEXEEFF: So, I don't know of any risk
8 estimates, though, for that. I mean, that would be an
9 interesting --

10 DR. BECKER: We've never quite dealt with that
11 on this Panel where something's metabolized to another
12 agent. We did with trichloroethylene, and we talked a
13 little bit about formaldehyde where it went through the two
14 pathways, but --

15 DR. ALEXEEFF: But I think then, the issue
16 would still be that the endogenous capacity to metabolize
17 acetaldehyde or to deal with acetaldehyde would be
18 different than the ability of the respiratory epithelium
19 to metabolize acetaldehyde.

20 DR. BECKER: Well, there are people in Mt. Sinai
21 in New York who think that acetaldehyde damages
22 mitochondria, and as the dose level rises, it leads to
23 liver dysfunction. And the reason why doesn't everyone
24 who drinks get liver pathology, they think it has to do
25 with differences in acetaldehyde metabolism. So, once I've

1 said that, I don't know what to do with it. I'm sort of
2 left with it. And I think I agree completely that based
3 on everything I know, the document's not seriously
4 deficient. I wouldn't know how to give you these
5 estimates, and I wouldn't know how deal with it. And
6 the animal data is very convincing for dose response
7 relationships.

8 DR. BYUS: I don't have anything substantial to
9 add to what everybody else said. It is disturbing that
10 we're extrapolating five orders of magnitude. That always
11 is disturbing, especially without any human data or
12 minimal human data. If there's some human data, it's
13 easier to do it. I feel much more comfortable doing it.

14 I agree about the metabolic -- the endogenous
15 production of acetaldehyde. I agree with your judgment,
16 but the contact aspect of the carcinogenesis is probably
17 the most important thing to consider. Again, I would do
18 the same thing. I would try make some calculation based
19 on how much you're inhaling at the low ambient levels.
20 How much that would perturb the acetaldehyde that's in
21 the cells lining the upper GI tract?

22 I would make that calculation to see what the
23 numbers came out to be. If they were ridiculously off --
24 assuming some degree of absorption, which you could
25 calculate, how much acetaldehyde would that be changing in

1 those cells that are the targets or potential for becoming
2 transformed.

3 DR. BECKER: The enzyme that metabolizes alcohol
4 is going to deliver a fixed amount over time. And you
5 could take the range using the range from the Swiss on
6 the one hand to the Japanese and Indians on the other
7 with various kms. I think it's all been done by Charlie
8 Lieber actually in an attempt to look at that.

9 DR. BYUS: At the very low levels of exposure
10 that we're talking about here down in the ambient levels,
11 what then percentage of the total acetaldehyde in the
12 cell would be coming from -- assuming some proportional
13 amount of absorption, what would then be coming from
14 inhalation? If it's some ridiculously small number,
15 this metabolic argument that's made by the Bakers and
16 other people, I think that would have a little bit more
17 weight against arguing against extrapolating down to those
18 low levels.

19 On the other hand, if it was some significant
20 percentage of the total acetaldehyde in the cell, if you
21 were raising it 10 or 15 percent, you could say, okay,
22 I could see that biochemically doing something. But if
23 you're only causing a tenth of a percent increase in the
24 total acetaldehyde inside the cell, I would think that
25 would argue for less. A hundredth of a percent, a

1 thousandth of a percent, you could say, it's unlikely
2 to have any effect. Do you see what I'm getting at?

3 DR. ALEXEEFF: Uh-huh.

4 DR. BYUS: Again, even when we're all said and
5 done, I'm not sure what we do with those numbers,
6 whether it would help me quantitatively making this five
7 orders of magnitude extrapolation.

8 DR. FRIEDMAN: Now, when you both have been
9 referring to this metabolic production, are you talking
10 about acetaldehyde that's brought by the bloodstream to
11 the cells?

12 DR. BYUS: It's in the cells. It's either
13 brought there or --

14 DR. BECKER: There's alcohol dehydrogenase in
15 many cells. I don't know whether -- it's certainly in the
16 brain, and it's in the liver, and whether it's in the
17 respiratory epithelium, I don't know.

18 DR. FRIEDMAN: Well, another thought that occurred
19 to me is that, let's say you drink some alcohol. And
20 you agree, that since you can smell it on someone's
21 breath, you're exhaling it. And if you're only concerned
22 about surface contact, if there's acetaldehyde also being
23 exhaled along with that, there must be some surface contact
24 due to that. And I wonder if that could be determined or
25 calculated.

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1 DR. BECKER: There was a series of articles
2 by Dr. Charles Lieber, L-i-e-b-e-r, of Mt. Sinai -- the
3 VA Hospital in New Jersey -- I think it's the VA in
4 New York. And he has a series of papers on those questions.
5 Maybe you can give him a call. And actually, I don't
6 think the smell on the breath is alcohol itself; it's
7 fusel oils and acetaldehyde, but maybe that is a
8 significant contact. I don't know. You could look at
9 that, because it fouls up the breathalyzer. The
10 breathalyzer is set for --

11 DR. FRIEDMAN: So it may be that a couple of
12 drinks, the amount of alcohol that you'd exhale past
13 the nasal epithelium would be far in excess of anything
14 you'd get from what we're talking about in the atmosphere.

15 DR. BYUS: The amount of acetaldehyde.

16 DR. FRIEDMAN: What did I say?

17 DR. BYUS: Alcohol.

18 DR. FRIEDMAN: Oh, I'm sorry.

19 DR. ALEXEEFF: It's possible. I don't know.
20 Alcohol is a respiratory tract carcinogen or upper
21 esophageal kind of carcinogen in humans. So, there might
22 be a reason that we can find if the dose is much higher
23 as you suggested as compared to acetaldehyde where we're --
24 the dose is much lower.

25 DR. FRIEDMAN: I'm wondering about the acetaldehyde

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1 dose in the expired air.

2 DR. ALEXEEFF: We'll look into it.

3 CHAIRMAN PITTS: Given the interest in this and
4 the importance of this, we'll assume that among --
5 regardless of what our final decision is, how we handle it
6 today, that will be addressed in the document.

7 DR. ALEXEEFF: Well, I think we need to follow
8 a couple of leads and we'll talk to Dr. Becker and
9 Dr. Friedman and see if it meets --

10 CHAIRMAN PITTS: Well, you can at least raise the
11 issue and say we looked at this and have not reached a
12 conclusion, but the issue has been raised, and you
13 followed some leads, which indicates that you won't
14 be sandbagged by someone coming in later and saying,
15 "Well, gee, you never discussed alcohol as a possible
16 source of acetaldehyde coming through the expired air."

17 You will look at it, and then the decision
18 can come after you've looked at it. But it should be
19 noted in the report that you have examined it. It is a
20 question. And then you might even say, unfortunately,
21 we don't know the following about the answer. We lack
22 the following information. Wouldn't it be nice to have
23 that? It's an area that might be worth looking at.

24 DR. BECKER: There's another way to look at it
25 is that there's literature of using acetaldehyde adducts

1 as the DNA adducts with acetaldehyde as a marker of
2 alcohol consumption. So, there's been two or three groups
3 that have tried to use that to get an estimate of alcohol
4 intake.

5 CHAIRMAN PITTS: I just have one point myself
6 that relates to the fate of acetaldehyde in the
7 atmosphere and forming PAN. It is the key source or
8 forming process of nitrate. So, at least a paragraph can
9 be put in here saying that's a fact that on the one hand,
10 we looked at the form -- acetaldehyde formed metabolically
11 from say possibly ethyl alcohol.

12 And then getting the atmospheric fate of
13 acetaldehyde to PAN, which has severe noncarcinogenic
14 effects in terms of eye irritation, lung, and so forth,
15 and just -- without going into the cancer implications.
16 I don't know that a cancer potency has ever been determined
17 for this. Certainly there's no doubt that it has strong
18 noncancer effects. And just a paragraph stating that, that
19 it's one of the aspects of acetaldehyde as a toxic air
20 contaminant. It forms a miserable substance.

21 DR. COLLINS: Put that in the human acute
22 toxicity?

23 CHAIRMAN PITTS: Exactly. And there's quite a lot
24 literature on this: (A) that it's formed. The chemistry
25 of it is clear, it is formed from acetadelyde. And if

1 want to make it in a smog chamber, that's one way you can
2 make it. And then the other is the fact that it's a
3 strong, powerful sitotoxicant, and we all know that
4 that's relevant.

5 Now, gentlemen, how do we want to handle the --
6 how would you care to go about handling the issue? We have
7 several options. I guess one of them is that we can
8 declare the report, as presented, and as given to us
9 initially, is acceptable, subject to significant
10 additions and modifications that have been addressed and
11 initiated by the Panel today. And the Panel will
12 be provided with -- before final action is taken on
13 findings and/or the report itself -- the Panel will be
14 provided with the initial document, the initial findings,
15 and the revised summary and document that have been
16 revised in accordance with our discussion today.

17 And I guess Bill Lockett's the one I want to ask
18 about this. Then a vote could be taken among the Panel
19 informally that -- do we agree with the revised version.
20 Would that legally meet the requirements of point one;
21 in other words, approving it with the revisions, as
22 indicated in our discussions and inputs generated from the
23 Panel in our discussions, to come back to the Panel
24 revised in that format, and actually have a phone or mail
25 ballot saying that we now agree that it's all

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1 satisfactory.

2 MR. LOCKETT: I'm not clear. I don't think we've
3 ever done a mail ballot before. My understanding is
4 that you have discussed on the record the kind of
5 changes and modifications you want in the report, and
6 that you have chosen -- I think, you, Mr. Chairman,
7 Dr. Seiber, and Dr. Friedman -- to kind of be a committee
8 of the Panel to review the changes to the report and
9 the changes to the findings.

10 Have you discussed the findings yet?

11 CHAIRMAN PITTS: No.

12 MR. LOCKETT: Okay. So, I would think for the
13 record you want to discuss the findings and the changes
14 that you want to them. And what I understand the staff
15 would do is to make the changes per the discussion for
16 the record to be reviewed by the three of you, if that's
17 in accordance with the Panel.

18 And then, when it comes to the findings, again,
19 the three would review the findings per the discussion
20 of the changes in the report; if that is fine, then I would
21 suggest that the findings be circulated among all the
22 Panel before you sign them off as final. Does that embody
23 what you were --

24 CHAIRMAN PITTS: Is that a satisfactory approach?

25 In your absence, Stan raised the question: He

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1 wasn't sure that we should go that far, basically, given
2 the substantive --

3 DR. GLANTZ: Yeah, I think --

4 CHAIRMAN PITTS: -- concerns.

5 DR. GLANTZ: Yeah. I think that the report,
6 it's not horrible, but I think enough issues have been
7 raised and things that people want added or sort of
8 shuffled around, and it's more than we usually have done
9 when we sort of accepted it, subject to minor tinkering.
10 I think there's a little more tinkering here.

11 So, I'm a little concerned about it. I mean, if
12 the rest of the panel wants to do that, I mean, I won't
13 stop it, but I would personally feel more comfortable
14 if we could kind of defer a final vote until we'd seen
15 the final document. Then I would think it could be voted
16 on and passed fairly quickly.

17 But if everybody else would rather do this other
18 thing, I trust the Chair and the others.

19 MR. LOCKETT: Well, it sounds like what you could
20 do is entrust it to the Chair and the committee of the
21 Panel. And if there are things that look like, no, you
22 really need to confer again with the whole panel, then
23 that could trigger a meeting. One other problem is trying
24 to schedule a meeting with all of you.

25 DR. FRIEDMAN: And maybe there'll be certain issues

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1 like this last one about the exhaled acetaldehyde.

2 DR. GLANTZ: But, then, aren't we really -- I
3 mean, aren't those substantive enough things that we
4 really need to have a vote on the final document after
5 all that has been revolved?

6 MR. LOCKETT: I think it depends whether or not
7 there's been adequate discussion on the record, so the
8 wording that you're working on is within the discussion
9 on the record.

10 Genevieve?

11 MS. SHIROMA: Yes. Some food for thought. I'm
12 putting my risk manager hat on here. I'm looking at,
13 down the road, once you are satisfied with the report,
14 how it will be used.

15 Today, it comes across to me as though you do
16 not find the report seriously deficient -- the science
17 that was used, the numbers that were used. Rather, you
18 would like to have some things conveyed a little
19 differently, clarification, some additional information
20 placed in the report. This information on the exhaling
21 of ethanol, acetaldehyde, and exposure is perhaps one
22 piece of the whole puzzle.

23 But in terms of looking at how we use the
24 report in the future for developing risk reduction control
25 measures for stationary sources, or whether it's looking at

1 further measures for tailpipe emissions -- just food
2 for thought. It appears to me that the report is in
3 pretty good shape, but you'd like to have some additional
4 clarification, a little extra information in there for
5 you. So, it would appear to me that if you could
6 delegate two or three Panel members to work with us on
7 this -- as far as the whole pictures goes -- and they
8 could assure that, for the record and from our working
9 with you, that all of your concerns are addressed in the
10 final report.

11 But it's just food for thought. My own opinion.

12 CHAIRMAN PITTS: Well, I would say, as one of the
13 two -- Seiber and myself -- I would submit everything you
14 submit to the other Panel members and say, "Here's what's
15 come in on Part A and the Executive Summary." I'd do
16 that in any case. Along with my evaluation, for example,
17 of what I thought of what had been done in Part A, but
18 I would just take it as a matter of course that the rest
19 of the Panel would see that and that it's important
20 enough that they do.

21 There would be no problem with that, would
22 there, Bill? I mean -- Mr. Lockett, that would be the
23 procedure we'd follow. So, we would certainly agree to
24 do that. Now, how does that strike you now, Stan? Are
25 you willing to go along with that?

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1 DR. GLANTZ: Okay. I'm mollified.

2 CHAIRMAN PITTS: Are you mollified?

3 DR. FRIEDMAN: Would this be by mail, you mean,
4 or be at the next meeting?

5 CHAIRMAN PITTS: Well, I'd mail you my
6 comments of what I saw, mail you what I thought of it,
7 and any proposed revisions of what I saw of the additions,
8 and see that each of you got that, and say, "Get back
9 to me in a week or ten days, or two weeks," something like
10 that, some reasonable time, and, "What do you think?"

11 And I'm very much interested in this alcohol,
12 this possibly metabolic transformation to acetaldehyde,
13 and the levels, a very interesting area.

14 It brings up a question. Stan, has anyone
15 actually measured acetaldehyde in the expired breath
16 of an alcoholic? I mean, this seems like it'd be pretty
17 straightforward. That should be a component of indoor
18 air pollution.

19 (Thereupon, the Panel members held a
20 simultaneous conversation which was
21 unreportable.)

22 CHAIRMAN PITTS: It's almost martini time.

23 MS. SHIROMA: And we can facilitate that for you.

24 (Laughter.)

25 CHAIRMAN PITTS: The martini?

1 MS. SHIROMA: Well. . .

2 (Laughter.)

3 MS. SHIROMA: In the documents, we would use
4 the strike out/underline format, have conference calls
5 as you see fit.

6 CHAIRMAN PITTS: Okay. Now, you have a clear-cut
7 sense of the seriousness of how certain things really
8 ought to be addressed, too, not casually. But it's a
9 significant question raised on the alcohol, significant
10 questions, I think, about ethanol as an alternate fuel,
11 what that implies, because this is a major concern, not
12 only for public health, but the regulatory agencies that
13 are involved, the whole thing. So, I think --

14 DR. ALEXEEFF: What Genevieve's been saying is
15 that our conclusions won't change, but there's some
16 additional paragraphs, or sections, or modifications to
17 be made to our report. But the actual conclusions or the
18 use of the report will not change, except in an
19 understanding way, a qualitative, total picture,
20 understanding way. So, that's why --

21 CHAIRMAN PITTS: Well, your conclusion might
22 change if you find that the alcohol conversion,
23 biochemical conversion to acetaldehyde might produce --
24 might transport to the cells, epithelium cells at a level
25 that dwarfs what might be coming in the other direction.

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1 DR. ALEXEEFF: I don't think it would change the
2 conclusion. It might add to the uncertainty and confusion
3 level. I mean, I don't know what the answer is. I don't
4 see how we could adjust the animal potency slopes
5 knowing that information.

6 CHAIRMAN PITTS: We've all agreed that that will
7 be discussed, and we'll get it back?

8 MS. SHIROMA: Yes. And at this point, if you have
9 any other instructions on the findings, then we can take
10 that. And we'll be reviewing this record as we work with
11 you fine-tuning the language.

12 CHAIRMAN PITTS: Okay.

13 DR. GLANTZ: I think there's two things in the
14 findings. I think one is the ethanol issue, which should
15 be in the findings. It's something that can significantly
16 impact, you know, what the potential total health impact
17 would be. I'd like to see some sentence on that.

18 CHAIRMAN PITTS: Absolutely.

19 DR. GLANTZ: And other thing is that I think
20 that some very boiled down version of this paragraph on
21 page 9-10 about the uncertainty should be worked in there,
22 too.

23 CHAIRMAN PITTS: Well, I think the findings
24 should reflect our discussion of the Executive Summary;
25 they should be included. For example, the ethanol -- the

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1 problems with ethanol as an alternate fuel, the
2 atmospheric fate of acetaldehyde to form PAN. That should
3 be in the findings.

4 MS. SHIROMA: Yes. And we definitely noted
5 those.

6 CHAIRMAN PITTS: So, the assumption is that the
7 major points of discussion here will be reflected in
8 the findings. That's what you're saying. That's fine.

9 MS. SHIROMA: That's fine.

10 CHAIRMAN PITTS: Any problem with that? All right.
11 Well, then, I guess the motion is subject to the
12 discussion that we've had concerning how this matter will
13 be treated. Do we approve the procedures as outlined?
14 Do I hear a motion to that effect?

15 DR. WITSCHI: So move.

16 CHAIRMAN PITTS: Is there a second to that
17 motion?

18 DR. BECKER: Second.

19 CHAIRMAN PITTS: Is there any further discussion?
20 All those in favor?

21 (Thereupon, all hands were raised.)

22 Opposed?

23 We're there unanimously.

24 MS. SHIROMA: Thank you so much.

25 We have a few more items for you.

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1 DR. ALEXEEFF: (Interjecting) I was going to
2 ask if the Chair could consider moving the ETS item up
3 to the front. We think it's going to be a rather short
4 informational item. And it's simply for the staff so
5 that the staff can return back -- fifth item (sic) on --

6 CHAIRMAN PITTS: Fifth item did you say?

7 Is that suitable? Okay. Fine. Please do.

8 Excuse me. Before you begin, Bill Lockett,
9 our guiding counselor, pointed out that we want to be
10 sure that the Panel approved the report subject to the
11 procedures discussed. Is that correct?

12 (The Panel replied simultaneously in the
13 affirmative.)

14 CHAIRMAN PITTS: Okay. Then, that is officially
15 on the record in that form. A good point. Thank you.
16 And Bruce raised that. Thank you.

17 Now, excuse me, Lauren, go right ahead.

18 DR. ZEISE: All right. I'm Lauren Zeise, and
19 I'm coordinating the ETS report for OEHHA. And at my
20 side is Amy Dunne, who is doing a good deal of work on
21 the report.

22 Have you had an update on ETS? It hasn't been
23 for a while. So, maybe if I can just run through the
24 time line a bit. We also had a workshop in October of
25 last year. And perhaps Dr. Becker, who's lead on the

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1 document, would like to also discuss that. I don't know
2 in what order you'd like to do things, Doctor.

3 DR. BECKER: Well, we had a two-day -- October
4 13th and 14th, we met in Oakland. There was extensive --
5 are you going to discuss some individual things from
6 it?

7 DR. ZEISE: I was just basically going to give
8 a time line. So, you could add to that.

9 DR. BECKER: We discussed the broad areas of ETS,
10 reproductive, cardiovascular, risk assessment. There was
11 a lot of interesting interchange. It was quite an
12 excellent meeting. And out of that, we opened up a
13 dialogue about the areas in controversy. Articles were
14 forwarded to me, which I forwarded to you, and back and
15 forth. And so, I thought we made a lot of progress
16 at the meeting. So, I think, for updating us, it would
17 be just to tell us about the time line as to how the
18 documents are coming. I don't think we need to get into
19 specifics.

20 DR. ZEISE: All right. Okay. Basically, what
21 we've done in terms of the document is we've divided it
22 up into different parts, because we were concerned that
23 certain pieces that were being addressed by multiple
24 authors might be hung by a particular author or in terms of
25 the review process.

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1 So, basically, we've developed a series of
2 documents, some of which are actually already in the
3 internal draft stage. There's a document on reproductive
4 and developmental effects, which is undergoing internal
5 review right now, also one on respiratory effects.

6 We have a document on other cancers, other than
7 lung, which is covering bladder, nasal, sinus, brain,
8 cervix, childhood leukemia. That is nearly complete
9 and ready for internal review.

10 We ran into an interesting issue with respect
11 to the exposure document, because, as we were developing
12 it and working through the details, we realized that we
13 were reproducing a lot of work that the US EPA has
14 already done -- an excellent document on covering
15 exposure. So, what we've done, we are proposing -- in
16 discussing with the ARB -- a restructuring of that whole
17 document. And basically, what we'd like to do is to
18 summarize the US EPA document, and then add to it issues
19 that are of particular concern in California.

20 So, we'll be discussing that with ARB staff.
21 Now, we expect the repro and respiratory documents to be
22 ready for external review sometime in July. We might be
23 able to beat that date. But given all of the other
24 demands on staff time, it might be as late as July that
25 we release those documents for external review.

1 Other cancers is ahead of schedule. We still
2 expect that it will be the summer before that document
3 is released for external review. Our cardiovascular
4 document, we're expecting sometime in the fall; and
5 the exposure document, as well, for external review.

6 So, towards the end of the year, we will have
7 all of the pieces, hopefully, together. But we will
8 expect to make significant progress over time on
9 particular pieces, and we look forward to hearing
10 your comments on our drafts.

11 DR. GLANTZ: If I could say one thing. I think
12 that your decision about the exposures is a good one.
13 I think the EPA did a very nice job. But there are a
14 couple of things that were presented at the workshop that
15 I think were highly relevant. Peggy Jenkins' data from the
16 ARB -- I was very impressed with that. I thought it was --
17 a lot of surprising results, in fact, as to what she came
18 up with, which shows some ways that California might be
19 a little different from the rest of the country, probably
20 because of the weather here.

21 Also, I think that the data from the California
22 tobacco surveys -- John Pierce did for the Department of
23 Health Services -- also were really a unique source of data.
24 It's California specific. So, I think, at least from my
25 point of view, that if you were to take the work that EPA

1 did and then add in the appropriate things from those
2 other two sources, that would probably be -- really lead
3 to a nice document.

4 DR. ZEISE: We fully intend to cover those.

5 CHAIRMAN PITTS: Are there other comments from the
6 Panel members?

7 DR. GLANTZ: I just had one other question.
8 Your plan is that these documents will be released for
9 external review, which I would take it is sort of like
10 the public comment period. You'll have the public comment,
11 then they'll come to us, much like the one we just
12 finished today? Is that the plan?

13 DR. ZEISE: Right.

14 DR. GLANTZ: And then, at the end, they'll all
15 be sort of stapled together into one --

16 DR. ZEISE: Unless one document is held up.
17 And if we need extensive work, maybe it would be useful
18 to provide the public with information --

19 DR. GLANTZ: The final version.

20 DR. ZEISE: Yeah.

21 DR. GLANTZ: That's a good plan.

22 DR. ZEISE: So, we're just seeing how the
23 documents make it through and what problems come up.

24 DR. GLANTZ: Okay.

25 CHAIRMAN PITTS: I'd be interested in seeing the

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1 original literature on the exposure side, and then
2 what you're doing with it. I'm really interested in the
3 chemical analysis, you know, the composition, what's out
4 there, and then the exposures.

5 DR. ZEISE: Yes. Would you like that actually
6 in the exposure assessment or if, in fact, EPA has
7 adequately covered --

8 CHAIRMAN PITTS: I'd like to see that. If I
9 could see that now. I'd just like to have it for
10 information, because so much of the things that we're
11 discussing wind up in ETS. And then, sort of be kept
12 up to date as you proceed in taking Peggy Jenkins' data.
13 I'd like to see that again, too. I'd really appreciate
14 that, because it's an area of great interest.

15 Okay?

16 DR. ZEISE: Should we circulate it to you, and
17 then you would circulate it to the Panel?

18 CHAIRMAN PITTS: I certainly think that the
19 Panel is interested. I see nods.

20 Genevieve, could you just see -- maybe Bruce
21 could take care of the circulation of that material to the
22 Panel.

23 MR. OULREY: Yes.

24 MS. SHIROMA: If everyone is interested, we'll
25 make sure and send it to each of you.

1 CHAIRMAN PITTS: Well, I think, generally, you
2 could say we're interested.

3 DR. GLANTZ: There's fairly large literature
4 out there on exposures. You're not asking for --

5 CHAIRMAN PITTS: No, I want the assessment.

6 DR. GLANTZ: So, you want the EPA document,
7 plus basically what Peggy Jenkins' presentation --

8 CHAIRMAN PITTS: Yeah.

9 DR. GLANTZ: You don't want them to have to go
10 searching for --

11 CHAIRMAN PITTS: I don't want 500 pieces of
12 information on this. But if you see one or two that
13 really look critical that come out of your yard --

14 DR. ZEISE: So, some of the key papers that
15 are particularly interesting.

16 So, what we'll do is -- and ARB already has lots
17 of that work, so we'll be working with you (addressing
18 Ms. Shiroma), and submission would come out through you.

19 MS. SHIROMA: Right. We'll get that information
20 to all of you.

21 CHAIRMAN PITTS: You understand we don't want a
22 stack of everything, but particularly a couple of key
23 references that your staff thinks is the latest stuff,
24 and you feel that way, we'll appreciate that.

25 DR. GLANTZ: I think the EPA did a really good

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1 job.

2 CHAIRMAN PITTS: Okay. And it's current.

3 DR. GLANTZ: It's very current.

4 CHAIRMAN PITTS: And that plus Peggy's.

5 DR. GLANTZ: Yeah.

6 CHAIRMAN PITTS: Okay. Thank you very much.

7 I appreciate that.

8 Now, we'll go back now to Item 2 on the agenda,
9 discussion of Committee report on the implementation of
10 AB 2728, Tanner.

11 MS. SHIROMA: Right. And what we have for you
12 today are a series of short presentations, and OEHHA also
13 has a part in this. What I thought I'd do is just spend
14 two minutes going over the terms, because we're going to be
15 giving you a status report on several pieces of
16 legislation. And we keep on talking about 1807, and 2728,
17 or 1731, and you never -- it gets real confusing. And I
18 just wanted to walk through the four pieces of legislation
19 that are key here.

20 And then Joan will give about a ten-minute
21 discussion. After that, I'll come back and give you yet
22 another discussion, and then the health folks will come
23 back up and give their portion of the presentation.

24 I think, overall, just our presentation
25 all together, will take maybe 20 minutes.

1 Okay. Again, just to we're all familiar with the
2 terminology, as you're very well aware of, we've had
3 AB 1807 now since 1984, and that's the Tanner legislation.
4 The Board has identified 18 substances as toxic air
5 contaminants. We've had a number of control measures
6 developed through this program.

7 Last year, AB 2728, by Tanner as well, was
8 adopted and signed. And that modified our AB 1807
9 program. It basically authorized ARB to identify the
10 189 hazardous air pollutants, the federal list, as toxic
11 air contaminants. Also, this Panel appointed
12 Dr. Seiber and Glantz to work with us on the new process
13 for taking these pollutants -- these substances through
14 this Panel. Okay.

15 Next slide.

16 Then, along with that, we have had the AB 2588
17 air toxics hot spots program. This was originally
18 sponsored Assemblyman Connolly. And that has been the case
19 since 1988. And after Joan's presentation, I'll be giving
20 you an overview of what this program is all about from
21 cradle to grave.

22 SB 1731 modified that program last year, which
23 was Senator Calderon's bill. He added a reduction
24 management element to it. He also added a risk assessment
25 guideline element to it. And there again, this Panel

1 assigned Drs. Byus and Pitts to work with us on this new
2 process.

3 So, we have the four pieces of legislation. At
4 this point, Joan is going to talk to us about what's been
5 going on with 2728, the Tanner bill that amended 1807
6 last year.

7 DR...DENTON: Thank you, Genevieve. Again, just
8 to repeat what Genevieve said, that AB 2728 required
9 the Board to identify all the federal hazardous air
10 pollutants as toxic air contaminants. And in April, the
11 Board did take that action. And at your last Panel
12 meeting, you appointed Dr. Seiber and Dr. Glantz to work
13 with us on ways to implement the program.

14 This afternoon, I'm going to give you a short
15 report on our discussions with Dr. Seiber and Glantz,
16 plans for future work of the Committee, and per Dr. Seiber's
17 request, you'll see that I make reference to the AB 2588
18 program. And Genevieve will be giving you this two-
19 minute update on the program.

20 So, first of all, the report on the discussions
21 with Dr. Seiber and Glantz.

22 Since the last Scientific Review Panel meeting,
23 the staff of ARB and OEHHA have met three times with the
24 Committee to discuss the process. And, as a consequence
25 of these discussions and in consultation with the Panel

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1 members, we are proceeding to prioritize all of the
2 substances on our toxic air contaminant identification
3 list into three different categories.

4 And in your folders, there is a series of
5 attachments that I'll be referring to. And Attachment 1
6 is the categorization of April, 1993's TAC identification
7 list.

8 So, this list actually spells out the
9 categories which we will be using to prioritize our
10 substances on the list. And the categories are high
11 priority, low priority, and no priority. And all of the
12 232 substances on the list will be placed in one of these
13 categories based on their scores in the prioritization
14 process.

15 Now, each substance will be prioritized using the
16 criteria found on Attachment 2. And per our discussions
17 with Drs. Seiber and Glantz, we have combined the cancer
18 and noncancer criteria.

19 And this list of nine different criteria differs
20 from the original criteria, which you approved, by the
21 addition of Categories 2, 4, and 9; that is, the
22 toxicological end points, the chronic, acute noncancer
23 effects, and the AB 2588 risk assessment considerations.

24 In addition, Category 5, which was originally
25 the reference exposure level availability, has been

1 replaced by chronic, acute noncancer effects.

2 And our next step is to work with the Panel
3 Committee to further delineate each category and assign
4 point scores to each one.

5 Each substance then will be prioritized using
6 this scheme and point scores, which we'll work out later,
7 and placed in one of the three categories listed on
8 Attachment 1.

9 DR. FRIEDMAN: Mind if I interrupt now with a
10 question?

11 DR. DENTON: Sure.

12 DR. FRIEDMAN: I'm just curious about this
13 no priority, where you say substances have not been
14 monitored in California. Is it conceivable that there might
15 be some toxic or dangerous substances just by chance, or
16 for some other reason, have not been monitored that should
17 not be ignored?

18 DR. DENTON: It could be. But we're also
19 considering if it's been reported as being emitted. So,
20 it's both: whether we have any data on whether it's
21 emitted and whether it's been detected or monitored in
22 California.

23 DR. FRIEDMAN: It sounds like ignorance is one
24 of the things that gets you into the no priority, rather
25 than assurance of safety.

1 MS. SHIROMA: I'll be describing this further
2 on our 2588 program, where we have 729 substances that
3 we're looking at in some fashion in California. I think
4 our attitude was that some of those pollutants on the
5 189 are not used or emitted in California and, therefore,
6 we wouldn't have -- there is no information and so, there's
7 no priority. And there may be a substance where we
8 haven't gotten to that pollutant yet and we're still in
9 the process of checking to see if it's there.

10 DR. GLANTZ: Yeah. My intention, and I think
11 Seiber's also, was that this was a place where you were
12 pretty sure it wasn't there. It wasn't so much ignorance
13 is bliss mentality, but like coke oven emissions is the
14 standard example. There aren't any coke ovens in
15 California. So, these are things which simply don't
16 appear to be, you know -- they're just not here.

17 DR. FRIEDMAN: There's good reason to believe
18 they're not here.

19 DR. GLANTZ: There's good reason to believe
20 they're not here, yeah, I would say. It wasn't just
21 that we don't know whether they're here or not. It's
22 where you're pretty sure they're not.

23 DR. FRIEDMAN: It might be worth adding to that
24 definition of no priority.

25 MS. SHIROMA: We could clarify that.

1 DR. GLANTZ: Yeah, I mean I think that was
2 clear -- that was our intent.

3 MS. DENTON: Yes. And also, this is a working
4 list. So, we will keep vigilant should something come
5 up that we haven't seen before. And also, these are
6 draft criteria. All of this information really is in
7 draft form.

8 We're also working to develop a document which
9 will contain all of the information we will be using
10 in prioritizing the substances. And this document will
11 contain two to five pages of exposure and health
12 information on each of the substances on that list.

13 And Attachment 3 is an example, using
14 beryllium compounds, of the information we plan to include
15 on each substance in the document.

16 In the first couple of paragraphs, it includes
17 some general information on the substance. And then
18 there's information on sources and emissions, ambient
19 concentrations, indoor sources and concentrations,
20 atmospheric persistence, AB 2588 risk assessment
21 information, potential hot spot exposures, and then health
22 effects information, as well as references.

23 We plan to incorporate in this document only
24 readily available and, where possible, California specific
25 information. Also, we plan to have this document completed

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1 and available for public comment sometime this fall, and
2 then present the document to the Scientific Review
3 Panel for your review.

4 I do want to mention one issue which we've
5 discussed quite thoroughly with Drs. Seiber and Glantz,
6 and also the other day with you, Dr. Pitts. And that is
7 the need to remain flexible with these criteria. Although
8 we're going to evaluate each substance based on the
9 prioritization criteria, there may be other factors which
10 we will need to consider in placing a substance in one of
11 the categories.

12 For example, as we discussed at the last
13 Scientific Review Panel meeting, we'll be working closely
14 with EPA on the development of MACT standards. And as the
15 EPA program evolves, there may be a need for our program
16 to accelerate the evaluation of one or more of the
17 substances on our list.

18 Next, I'd like to just mention what our plans
19 for the future work with Drs. Seiber and Dr. Glantz are.
20 With your concurrence, our next step is to work with the
21 two Panel members to delineate the criteria that we have
22 put forward. And we'll be using these criteria in the
23 prioritization process. So, we'll not only delineate
24 the criteria, but also assign point scores to each
25 criteria. Unless if you have any questions, I will now

1 turn it over to Genevieve, who's going to give you
2 a short presentation on the AB 2588 program.

3 MS. SHIROMA: By the way, I wanted to give credit to
4 Dr. Glantz on the idea of updating what I keep
5 referring to as the Green report, which contains a two
6 to five page summary of each pollutant on our 1807 list,
7 which kind of provides the foundation of giving background
8 knowledge of all the pollutants and helping us
9 prioritize. So, that was a great suggestion and we're
10 following through on that.

11 At this point, I want to give you an overview
12 of the air toxics hot spots program so that, there again,
13 you have a frame of reference for this important program
14 and how your Panel fits into the program and responsibility
15 that you will have now in the air toxics program.

16 This flow chart should also be in your packet.
17 I think it's Attachment No. 4. When Assemblyman Connelly
18 introduced the bill and it was passed, it was to fill
19 what was perceived to be a void in the air toxics program,
20 in that we didn't have knowledge of the specific facility
21 sources on a statewide basis. We didn't have knowledge
22 of hot spots types of exposures and emissions. This
23 program was formulated to fill that void.

24 And we're well into the program now. If you start
25 at the left-hand side of the flow chart, basically what

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1 the program requires is that facilities submit plans and
2 reports to districts. And these are reports and plans
3 for terminating emissions inventory of each specific
4 facility. We now have up to 30,000 facilities which are
5 subject to the program. I've mentioned that there are
6 729 pollutants included in the program. They're divided
7 up where, in some cases, a company will do a source test;
8 in some cases, it's an emission estimation. In some
9 cases, it's simply a checklist. Do you use or produce
10 this pollutant?

11 The facilities submit those plans reports
12 to the districts for determining what their emissions
13 are, the toxic emissions. The districts review the
14 information, assure that it is QA/QC. Then, two things
15 happen to that information. First of all, it's forwarded
16 to the Air Resources Board for our statewide comprehensive
17 inventory. And we refer to our ATES inventory. It's just
18 an acronym, but it's our statewide comprehensive
19 inventory. The districts also use the inventory to
20 prioritize facilities. In other words, they use this
21 information to determine whether or not the facility needs
22 to go on and do a risk assessment.

23 In this prioritization they look at the emissions,
24 the potency of the substances, perhaps the proximity of
25 neighbors, and the meteorological types of conditions

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1 around the facility.

2 With that screening calculation, they specify
3 which facilities must then go on and do the risk
4 assessment.

5 Those facilities are placed into this high
6 priority category and then go on and use the algorithms
7 provided by the Office of Environmental Health Hazard
8 Assessment to prepare a risk assessment. Now, this is
9 a key juncture, because now, with 1731, this Panel
10 becomes involved in this step, in that you will be working
11 with the Office of Environmental Health Hazard Assessment
12 on developing risk assessment guidelines, which they will
13 adopt, for this part of the program.

14 Up until now, the facilities and the districts
15 have been using guidelines for conducting the risk
16 assessment, and these guidelines were produced through the
17 California Air Pollution Control Officers Association.

18 Okay. Depending on the outcome of the health
19 risk assessment calculation, a facility may or may not
20 need to notify the public, the surrounding public that
21 is exposed by the facility's emissions.

22 And this is where risk management decisions come
23 into play. Each of the districts goes through a
24 process of determining at what level does a facility need
25 to notify. I should also mention that there are
notification requirements for both cancer and noncancer

1 effects. You had an earlier discussion about RfCs for
2 acetaldehyde. The law requires that both cancer and
3 noncancer effects be assessed.

4 And the districts are well under way in choosing
5 the risk management level at which facilities need to
6 notify.

7 If a facility then needs to go on and notify,
8 there's a whole process for notifying the public through
9 either public meetings and/or -- and usually both --
10 public meetings and letters to individual households,
11 and also letters at workplaces.

12 The only district that has gone through a full
13 notification has been the Bay Area Air Quality Management
14 District. The other districts are anticipating going
15 through this process later on in the calendar year.

16 A new element added by 1731 is this risk reduction
17 phase. That was really the last link that was needed in
18 the program. The facility goes on and notifies the public
19 that they are posing a significant health risk. Then,
20 with this new legislation, they are required to determine
21 how they will reduce their risk below that level of
22 significance. And there's a five and ten-year time frame
23 for doing this. And the responsibility rests upon the
24 facility to come up with risk reduction audit measures.
25 The law also requires the Air Resources Board to provide

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1 assistance to smaller businesses in this endeavor.

2 And in that endeavor, basically, our staff
3 becomes process engineers, looking at the various
4 processes, looking at substitution of materials,
5 pollution prevention, the whole gamut of different kinds
6 of options for reducing risk.

7 Okay. So that, in a nutshell, is the program,
8 the full program for dealing with air toxics hot spots.

9 At this point, George and Melanie will be going
10 over the 1731 requirements for risk assessment
11 guidelines, and how that also meshes back with what
12 Joan was talking about on 2728, in terms of the process
13 we are using for health values.

14 DR. ALEXEEFF: Okay. Now, unfortunately,
15 there will be some overlap in our discussion, and we'll
16 just try to go quickly over that, and it will help
17 everyone memorize all of these numbers of these bills
18 and legislation involved.

19 The way we were divided up in terms of our
20 committees and working with subcommittees of the SRP
21 was in those functions under AB 2728, which is the
22 hazardous air pollutants, and those functions under the
23 guideline development, or 1731.

24 But in terms of actual workload, there's a lot of
25 overlap between those two laws. So, it doesn't make sense

1 just to divide it up by legislative things. We should
2 do it by what makes sense in our workload working with
3 the Panel members.

4 So, the original suggestion was to develop
5 health assessment values for 2728. But there are some
6 additional health assessment values that fall under SB 1731.
7 So, we've, in our discussions with Dr. Glantz and
8 Dr. Seiber on the one hand for 2728, with Dr. Byus and
9 Dr. Pitts on the other hand for 1731, we decided to go
10 ahead with this kind of a division of work. That is,
11 we will develop three health assessment value documents,
12 and that will overlap the two programs.

13 Now, let me step back one more step. Under
14 the hazardous air pollutant law that was adopted as part
15 of the Clean Air Act, and then in April, the Air
16 Resources Board identified 189 chemicals as toxic air
17 contaminants. So, previously, we always had health
18 assessment values with these toxic air contaminants. So
19 now we have 18, through formaldehyde, with health
20 assessment documents and values.

21 Now we have an additional -- somewhere around
22 180 or so of compounds identified by the Air Resources
23 Board, because that was required by this law.

24 But no health assessments are here to go along
25 with those numbers. So, part of this process is trying to

1 Come up with what interim health assessment values can
2 we come up with until these other chemicals have gone
3 through the process; so that, you know, the whole purpose
4 of the legislation was to move more quickly and to
5 consider lots of chemicals and mixtures for control
6 strategies.

7 But if we don't have health assessment values,
8 it's hard to do that. So, what we decided to do was to
9 develop three documents. The first one is a cancer
10 document. And what we will do is summarize all of the
11 different numbers that have been developed by
12 different agencies, different parts of Cal-EPA, US EPA,
13 and different organizations within US EPA, and provide
14 the description of how they came up with that information
15 what the level of confidence we have in that data, or some
16 sort of system like that, and a description of what's
17 involved in their calculations, and then also a tabulariza-
18 tion of all the calculations.

19 And we'll do it first for the cancer values, and
20 then for chronic reference exposure levels, and then for
21 acute reference exposure levels.

22 Now, by the time we get to the chronic and the
23 acute, we'll also be discussing a lot of methodological
24 issues, like we were discussing before about this
25 reference concentration, and how much of a certain factor

1 to use. We'll have to come to some sort of, you know,
2 discussion of those issues as to, you know, whether we
3 should adopt some of these methodologies or these
4 calculations.

5 So, in that sense, I think it's going to be
6 very helpful, particularly for the acute reference
7 exposure level, because that's an area where there's no
8 adopted methodology at all, anywhere. So, this will be
9 the first time that we'll be actually discussing that
10 issue. And I think that's going to be very exciting.

11 On the next slide, now we're going to focus on
12 the cancer document, which will be our first document.
13 We will -- we built a hierarchy. So, if there are health
14 assessment values developed by different agencies, this
15 is the hierarchy that we are going to present in our
16 summary document, which will go through public comment,
17 workshop, and SRP review. And it's not as if this is the
18 final thing, this is just the beginning.

19 But the hierarchy we're going to present will be,
20 first, if there's a toxic or contaminant document and
21 a number, that'll be the number chosen. If there isn't,
22 but there's one developed under the Proposition 65
23 program that went through our Scientific Advisory Panel,
24 that one will be used. And then, third, the next one will
25 be a US EPA IRIS value. And then, fourth, there's a number

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1 of other different organizations and values, but we
2 don't have to get into the particulars right now.
3 The bulk will be covered in 1, 2, 3. And we're talking
4 somewhere in the neighborhood of a hundred, a hundred or
5 so chemicals. Okay? So, it will be a lot of numbers.

6 On the next slide, just to reiterate, we'll
7 be drawing chemicals, not just from these HAPs, but
8 we'll also be looking at chemicals on the hot spots list.
9 So, we'll just put them also in the categorization process
10 as well. And what we'd like to do is have these programs
11 sort of interact with each other and help each other,
12 so that, if we -- as we go through this process, if we
13 find a cancer risk assessment is poor, we'd like to be
14 able to make sure that the TAC program is aware of that
15 and it will help in its prioritization scheme, you know.

16 So, hopefully, there may be some that are bumped
17 over. If the cancer number is good, in the sense that
18 if the data that is available and the risk number they
19 calculated is the best that you can come up with -- I mean,
20 we don't see much improvement -- then, it may not make
21 sense to take it through the TAC process right away.
22 There won't be much change in the way we do it.

23 Like the acetaldehyde value we went through,
24 was it worth -- looking back, you know, we could evaluate
25 the worthfulness of the resources used to come up with a

1 value of 4.8 versus 2.2. You know, it might be better
2 to work on something where there's no value first, that
3 kind of -- an interaction with the programs.

4 The next one just kind of gives an explanation
5 of how we're going to build these -- this cancer
6 document in discussions with Drs. Glantz and Seiber; even
7 though it's a cancer document, they'd like us to sort of
8 briefly mention any noncancer -- the major noncancer
9 effects, just to keep everybody sort of straight as to
10 what the effects are. It'll just be a brief statement.

11 And then the cancer review will be fairly
12 extensive. It will be the heart of our cancer risk
13 assessment with the actual data, the studies used, the
14 end points, the cancer end point, the number of animals
15 responding at each dose level, how the calculations were
16 done, you know, if pharmacokinetics was used, all those
17 kinds of issues summarized as clearly as possible so
18 that it takes up as little space as possible.

19 And then there will be an exposure discussion,
20 which we'll get primarily from the Air Resources Board.

21 So, we had an example that we put together on
22 beryllium, which I'm not going to go through right now.
23 But this is the first time even the subcommittee members
24 actually saw the extent of this product. But at our next
25 subcommittee discussion, we'll probably discuss this and

1 whether or not this example is useful.

2 And you can see that even summarizing it as
3 briefly as possible, it still comes out to be, you know,
4 eight pages. So, if we have a hundred chemicals eight
5 pages long, and that's the appendix, plus -- it's going to
6 be a rather lengthy document.

7 I don't know -- beryllium was chosen essentially
8 for no particular reason. It was just a good chemical to
9 choose. So, maybe other ones won't be as lengthy.
10 But I think the idea was to choose one where there was
11 a lot of information. So, many of the chemicals will
12 maybe be only one or two pages long, because there's very
13 little information.

14 Okay. That's how we're going to be dealing
15 with the health assessment value portion of it..

16 Now, Dr. Marty is going to go through and
17 explain how the other aspects -- the rest of the 1731
18 program, which is our guidelines process.

19 DR. MARTY: My name is Melanie Marty. This
20 first slide again points out the legislative mandates that
21 are interconnected for OEHHA to develop risk assessment
22 guidelines for the air toxics hot spots program.

23 SB 1731 is the law that mandated this, and it
24 was passed last fall. Currently -- if I could have the
25 next slide, please. Currently, the hot spots program is

1 being implemented. Facilities are still providing
2 emissions inventories, and the districts are prioritizing
3 facilities, and health risk assessments are being written
4 and submitted for review.

5 And as Genevieve mentioned earlier, the CAPCOA
6 air toxics hot spots risk assessment guidelines is the
7 guideline generally being used, and that is this document
8 here (displaying document).

9 I would like to add that OEHHA has had a lot of
10 input into this guideline in terms of cancer potency
11 factors and reference exposure levels that are currently
12 being used, as well as the exposure assessment algorithms.
13 And while the OEHHA guidelines are being prepared pursuant
14 to SB 1731, the air toxics hot spots program is not going
15 to come to a screeching halt. It's going to proceed as it
16 is currently proceeding during the development of the
17 OEHHA guidelines.

18 And I'd like to also say that, thus far, OEHHA
19 has received 649 risk assessments to review under this
20 program. And we have reviewed a total of -- well, it's
21 actually about 279 now. So, that's over the last couple of
22 years. So, we're talking about a large number of risk
23 assessments and a large number of facilities that need to
24 have guidelines developed and be applied to these
25 facilities.

1 Okay. Next slide.

2 MS. SHIROMA: I was just reminded. What I
3 neglected to say in my presentation is that the OEHHA
4 has a very specific role on reviewing risk assessments.
5 The Act actually says that OEHHA is to review all these
6 risk assessments and provide recommendations back to the
7 districts of each facility's risk assessment. So, they
8 are looking at each one.

9 DR. MARTY: Okay. Task 1 is what George just
10 presented, and that is to compile and prepare documents
11 for the cancer potency values, and chronic reference
12 exposure levels, and the acute reference exposure levels
13 that we will end up putting into the guidelines for use
14 in health risk assessment for the hot spots program.

15 So, I'm not going to go over that again, since
16 we've already done that.

17 Task 2 is to prepare documentation for the
18 exposure assessment model that is used in the risk
19 assessment guidelines. Currently, we have an exposure
20 assessment model which OEHHA has had some input in the
21 beginning with the CAPCOA guidelines. We have that model
22 to work with, and we are considering using that model.
23 We also are evaluating the Department of Toxic Substances
24 Control's CalToX model for use in the hot spots program
25 to see if we can take any portions of that model and

1 incorporate it into the OEHHA risk assessment guidelines.

2 The CalTox model essentially looks at
3 intermedia transport of chemicals from one environmental
4 compartment to another. For instance, from soil to air,
5 air to soil, soil to water, water to air, et cetera. And
6 it uses a different approach than is currently used in
7 the CAPCOA guidelines.

8 So, we'll be evaluating that.

9 Resources are also being expanded by ARB to
10 develop intermedia transfer factors that describe the
11 transfer of chemicals, specific chemicals, between air
12 and water, for instance, and even between soil and food
13 crops, and food crops and animals, and then animals to
14 humans.

15 These resources and the results of these analyses,
16 which are being done at UCLA and Lawrence Livermore Labs,
17 will be used in OEHHA's guidelines to fine tune the
18 exposure assessment process.

19 For Task 3, it's to develop a user friendly
20 computer program for PCs for facilities to conduct their
21 own risk assessments. There are currently two programs
22 available which are being used right now in the hot spots
23 program. One was developed by ARB, and it's their health
24 risk assessment program, and it incorporates exposure
25 algorithms from the CAPCOA guidelines into a nice user

1 friendly format, and people can just plug in results of
2 their air dispersion model, get exposure and risk
3 calculations out of the computer.

4 There's another model, ACE2588, which was
5 actually developed by the Santa Barbara Air Pollution
6 Control District, which uses the same exposure algorithms,
7 but puts on the front end an air dispersion model, so you
8 just have to start with the engineering parameters and
9 emissions estimates, and then you end up running it
10 through the program and get a risk number out the other
11 end.

12 These models have proved to be quite useful in
13 the program and implementing the program, so OEHHA would
14 like to have a model that goes along with our guidelines
15 for people to be able to do the risk assessments.

16 Task 4 is for OEHHA to develop an uncertainty
17 analysis procedure for the risk assessment guidelines.

18 SB 1731 specifies that the OEHHA guidelines
19 contain guidance on probability based approaches to
20 risk assessment. We are, as a result of SB 1731, developing
21 guidance on how to conduct uncertainty analyses,
22 emphasizing the multipathway exposure analysis that is
23 done currently with the risk assessment.

24 Currently, we use a point estimate based approach
25 in the exposure assessment, and that is to say that for each

1 parameter that goes into the exposure analysis, we use
2 a single value. For instance, we have the reference
3 human who weighs 70 kilograms, breathes 20 cubic meters
4 per day, drinks two liters of water per day, eats a
5 set value of vegetables per day. And that is the person
6 for whom the risk is calculated.

7 But, obviously, we don't all weigh 70 kilograms,
8 and we don't all breathe the same rates. So, an
9 uncertainty or probability based approach would involve
10 inputting a range of values for each parameter that goes
11 into the exposure assessment, or at least for those
12 parameters that seem to make a difference in the outcome.

13 As a result, we have to develop the ranges of
14 values for those parameters, and we have to determine
15 what the distribution of those values is within each
16 range, and then use a statistical method to come up
17 with a range of doses and a range of risks at the end
18 product of the risk assessment.

19 We are considering a Monte Carlo type of
20 approach, although that has not been completely worked
21 out. In doing so, we do allow use of information relating
22 to population distributions and physiological parameters,
23 like breathing rates, body weights, behavioral
24 characteristics -- like mobility patterns, activity
25 patterns -- as well as microenvironmental characteristics,

1 such as what the -- how you characterize environmental
2 compartments that immediately surround a facility that is
3 being examined.

4 The risk manager then is provided with more
5 information on which to make decisions, and there is a
6 quantification of uncertainty, rather than us saying at
7 the end of the risk assessment, well, here's the number,
8 and we know there's a lot of uncertainty.

9 So, those are the benefits of doing an uncertainty
10 analysis. And another benefit might even be actual
11 reduction in the uncertainty.

12 DR. GLANTZ: Of course, Melanie, you can be
13 uncertain about the levels of uncertainty, too.

14 DR. MARTY: Absolutely. That's quite true.
15 Okay. We expect to conduct a literature search and use
16 outside experts to help us develop ranges and distributions,
17 and also statistical treatments of information.

18 And this slide just shows you the types of
19 parameters. There's many, many. This is just an example
20 of a couple of them that go into the exposure algorithms.
21 So, you have body weight, physiological types of
22 parameters. You also have physicochemical types of
23 parameters that go in, such as organic carbon partition
24 coefficients, fraction of organic carbon in soil that
25 end up impacting the dose estimates and, therefore, the

1 risk estimates in that exposure.

2 And rather than using point estimates, we'll be
3 looking at which parameters we can actually input ranges
4 that we can get from the literature. And we will also
5 conduct a sensitivity analysis to determine where we
6 should focus our efforts, so that it may not be
7 necessary to have a range for each and every parameter.

8 DR. ALEXEEFF: May I make one point? I know
9 you're close to the end.

10 The model that we're using takes into account
11 all of the monitoring that might occur by the Air
12 Resources Board, or the facility, or the air district.
13 So, what happens, we're not just monitoring for the
14 ambient concentration or the amount that's coming out of
15 the stack. But in addition to that concentration, there's
16 information that much of the stuff in the air,
17 particularly for lipid soluble compounds, can get into
18 other biospheric pathways and impact humans again.

19 So, that's where a lot of these parameters come
20 from, particularly from the lipophilic compounds. For the
21 other issues, as we indicated in our risk assessment on
22 acetaldehyde, where we had a 70 kilogram breathing a
23 certain rate, for the inhalation exposure, that person
24 will be moving around and not be right next to that
25 facility. For our acetaldehyde document, we were looking

1 at the statewide average. But in this case, we're talking
2 about people near some facility, a point source. So,
3 they're going to be moving in and out of that point
4 source's range. And that's the kind of information to
5 provide. Right now, we assume they stay right near that
6 point source.

7 So, this will give them more, hopefully more
8 accurate interpretation of what the exposure is.

9 CHAIRMAN PITTS: Well, let me ask you a quick
10 question.

11 In this example, how would acetaldehyde fit
12 in terms of its possibly being formed in vivo from
13 methyl alcohol? In other words, if another exposure
14 route -- r-o-u-t-e -- would that be in here?

15 DR. ALEXEEFF: No. No, because we would still
16 be looking at the excess contribution from the facility,
17 unless somehow there was a threshold phenomenon involved,
18 and it was building on that, then we might have to consider
19 the endogenous aspects of it. But, in this case, we're
20 just looking at additional cancer -- excess cancer rate
21 from the facility. So, the endogenous alcohol concept
22 would not be added in there.

23 It could be for the range of susceptibility some-
24 how. If we felt that some people were at greater risk
25 because of alcohol consumption or maybe we found out that

1 the acetaldehyde metabolism rate differs for different
2 individuals, we might then have a different range of
3 distribution for a response somehow. But --

4 DR. MARTY: That's my next point actually.

5 DR. ALEXEEFF: Oh, I'm sorry.

6 DR. MARTY: In addition to the ranges and
7 distributions of exposure parameters, we would also like
8 to consider evaluating the variability in response between
9 different individuals to a given chemical. So, we know
10 that there are humans that are susceptible to chemical
11 carcinogenesis through, you know, a variety of mechanisms.

12 We would like to be able to include that kind of
13 thing in the uncertainty analysis for the risk assessment.
14 That's going to be a bit more difficult, because the data
15 is going to be a little bit harder to come by.

16 DR. BECKER: The problem with this, is that
17 they'll spend so much time in court, because every person
18 who receives a notification and has a cancer in that
19 community is going to --

20 (Thereupon, there was a pause in the
21 proceedings to allow the reporter to
22 replenish her shorthand paper.)

23 DR. BECKER: I just might ask it as a question,
24 and that is, don't you anticipate that this is going to be
25 a tort process, and that the legal aspects of this might

1 just get out of hand and you wind up spending all your
2 time in court.

3 MS. SHIROMA: I think this question was
4 anticipated. First of all, liability is out there,
5 certainly, for a facility. But the way that the program
6 is being implemented in terms of identification, I think
7 that the main goal was to educate the public. And the Bay
8 Area has had the first-hand experience with this; and,
9 so far, has been able to come through it in a fashion that,
10 one does notify the public of what they're exposed to.
11 The company themselves are in the process of reducing
12 their emissions. And so far, we haven't landed in court
13 with many, many lawsuits. And we have a notification
14 guideline, which describes to the districts and to the
15 companies a reasonable way to approach the public and let
16 them know what is going on with the company, what they're
17 being exposed to, and what that means.

18 And so far, with the 70-year lifetime, 20
19 cubic meter, so forth type of conservative estimates,
20 we've been able to come through that pretty well.

21 But liability is always out there, and we
22 acknowledge that.

23 DR. MARTY: Okay. One more thing about the
24 uncertainty analysis. We do not anticipate at this time
25 including estimates of uncertainty around the cancer

1 potency factors or the reference exposure levels.

2 Part of the reason for that is that the
3 California cancer guidelines are still in the process of
4 being updated, and that type of information is going to
5 be considered in those guidelines, and we can't really
6 come out with something before they come out. So, that's
7 one of the issues that we're dealing with now.

8 And the last slide just shows really the
9 public input aspects of the whole SB 1731 OEHHA guidelines
10 process. The law does provide for input from CAPCOA,
11 so we will continue to meet with CAPCOA and they will be
12 reviewing working drafts of the guidelines as well.

13 And I might add at this point that ARB is going
14 to get -- we're going to be taking some resources from
15 ARB for the dispersion -- air dispersion modeling
16 aspects of the guidelines, since that is their expertise
17 and not ours.

18 We also provide for review by the public and the
19 SRP of working drafts of the guidelines, and we'll be
20 having public comment periods and public workshops,
21 and all comments will be considered. OEHHA will revise
22 the guidelines before presenting them to our Director for
23 adoption by OEHHA.

24 So, if there are any questions. . .

25 CHAIRMAN PITTS: Thank you. Questions? Stan,

1 do you have any comments? Peter? Dr. Becker?

2 DR. BECKER: No, I just think it's incredible.
3 If it's man-caused, there's a tort there. And I'm just
4 concerned that it's going to -- at least two that I've
5 seen that came out with some risk assessment, it's going
6 to be very difficult. I would anticipate it getting
7 bogged down in the legal aspect, because there's an
8 exposure and it's very hard -- we don't know what --
9 fundamentally, we don't know what causes cancer, so if
10 you're going to use cancer and you don't know what causes
11 it, then if a person has cancer and there's exposure
12 to something, and there's one molecule and it's man-
13 caused, then the whole thing is going to just get wrapped
14 up in some sort of legal problem. I wish there was some
15 way around that.

16 DR. ALEXEEFF: What has happened thus far has
17 not -- well, I won't say it hasn't resulted in any lawsuits,
18 because I have been intimately involved in that. But the
19 lawsuits haven't directly impacted us. Instead, what has
20 happened is that many facilities, after evaluating their
21 risk, have -- and they're allowed to do this -- in
22 their notification letter, explained the, you know, what
23 their plans are for reducing risks or what they think the
24 real risk is. You know, they have the alternative to
25 provide their view of what the risk assessment might be.

1 And the way it has tied in a little bit to the
2 legal system, just for your information, is through
3 Proposition 65 if the risks have found to be above one in
4 100,000, there have been some legal cases filed by --
5 Prop 65 allows a person filing the case to receive
6 some of the fine money. So, there is an incentive
7 to file some cases.

8 So, there's been this indirect impact. But it
9 hasn't resulted in bogging down the process in terms of --
10 in terms of our -- our workload. But, you know, it's
11 happening.

12 DR. BECKER: Good luck.

13 DR. MARTY: Thank you.

14 MS. SHIROMA: Unless there are other questions,
15 Dr. Pitts, do you want to discuss the schedule for the
16 next few months, and what we might have next? We're going
17 to continue with the two subcommittees, and we'll be
18 periodically coming back to the Panel and briefing you on
19 our work in progress. The next substance, I believe, is
20 lead.

21 We just held a public workshop. We've got a
22 comment period we're going through. We'll be updating
23 the report, and then bringing that to the Panel. And
24 we're looking at late August or early September as probably
25 being ready to bring that to the Panel.

1 DR. BECKER: And the interesting part is that
2 it will be the first time the Committee has dealt with
3 a noncancer health outcome.

4 MS. SHIROMA: Right.

5 DR. BECKER: So, that will be interesting.

6 MS. SHIROMA: Bruce indicated that he can poll
7 all of you later individually on your calendars.

8 CHAIRMAN PITTS: In terms of meetings?

9 MS. SHIROMA: For the next meeting.

10 CHAIRMAN PITTS: I'll make two very brief
11 comments. One is, I think what you're saying on 1731
12 now, this is actually bringing in more of a refined
13 approach to the whole subject of exposure and risk
14 assessment. And the kind of information that, for example,
15 interests me is the UCLA group. I know the investigators.
16 They're first class. They're developing the sort of
17 database for -- a state-of-the-art database for
18 transport of these chemicals, intermedia transport -- soil,
19 air, water. And up to now, it's been pretty much, well,
20 take a number. And they're working on this in an ARB
21 contract. And again, I'd like to see if you'll be thinking
22 about looking at a spectrum of the population rather than
23 the 70-year -- they're very young, very old. I'll never
24 forget when you were talking about ethyl parathion, pointing
25 out that kids up to six months old are very different in

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1 their reaction to ethyl parathion, the metabolic
2 approach to that. I think that's really an important
3 aspect. It's more complex, but it's also going to be
4 providing more useful information, a framework.

5 The second point, I want to thank the staff,
6 the members of the OEHHA and the ARB, for their
7 presentation today. I think it was very useful or
8 helpful, and for their courtesy in doing this, and also
9 the Panel members for their interreaction. It was a very
10 interesting day, and my appreciation to all of you.

11 MS. SHIROMA: Thank you.

12 CHAIRMAN PITTS: And the meeting's adjourned.

13 (Thereupon, the meeting was adjourned
14 at 5:25 p.m.)


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CERTIFICATE OF SHORTHAND REPORTER

I, Nadine J. Parks, a shorthand reporter of the State of California, do hereby certify that I am a disinterested person herein; that the foregoing meeting of the Scientific Review Panel was reported in shorthand writing by me, and thereafter transcribed into typewriting.

I further certify that I am not of counsel or attorney for any of the parties to said meeting, nor am I interested in the outcome of said meeting.

IN WITNESS WHEREOF, I have hereunto set my hand this 24th day of May, 1993.


Nadine J. Parks
Shorthand Reporter